Gene Technology Regulations 2001 2001 No. 106

EXPLANATORY STATEMENT

Statutory Rules 2001 No. 106

Issued by authority of the Minister for Health and Aged Care

Gene Technology Act 2000

Gene Technology Regulations 2001

Subsection 193(1) of the *Gene Technology Act 2000* (the GT Act) provides that the Governor-General may make Regulations prescribing matters:

(a) required or permitted by this Act to be prescribed; or

(b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.

Subsection 4(1) of the *Acts Interpretation Act 1901* provides that:

(1) Where an Act (in this section referred to as the Act concerned), being:

(a) an Act enacted on or after the date of commencement of this section that is not to come into operation immediately upon its enactment; or

(b) an Act enacted before the date of commencement of this section that did not come into operation on or before that date;

is expressed to confer power, or to amend another Act in such a manner that the other Act, as amended, will confer power, to make an appointment or to make an instrument of a legislative or administrative character (including rules, regulations or by-laws), then, unless the contrary intention appears, the power may be exercised, and anything may be done for the purpose of enabling the exercise of the power or of bringing the appointment or instrument into effect, before the Act concerned comes into operation as if it had come into operation.

Section 74 of the *Gene Technology Act 2000* provides that:

(1) The regulations may declare a dealing with a genetically modified organism (GMO) to be a notifiable low risk dealing for the purposes of this Act.

(2) Before the Governor-General makes regulations declaring a dealing with a GMO to be a notifiable low risk dealing, the Regulator must be satisfied that the dealing would not involve the intentional release of a GMO into the environment.

(3) Before the Governor-General makes regulations declaring a dealing with a GMO to be a notifiable low risk dealing, the Regulator must consider the following matters:

(a) whether the GMO is biologically contained so that it is not able to survive or reproduce without human intervention;

(b) whether the dealing with the GMO would involve minimal risk to the health and safety of people and to the environment, taking into account the properties of the GMO as a pathogen or pest and the toxicity of any proteins produced by the GMO;

(c) whether no conditions, or minimal conditions, would be necessary to be prescribed to manage any risk referred to in paragraph (b).

The object of the GT Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs. The Regulations give effect to the objects of the GT Act by providing further information about definitions in the GT Act; describing exemptions under the legislation; setting out the dealings with GMOs that are notifiable low risk dealings and the conditions which will apply to such dealings; describing the types of information that must by an applicant for a licence to deal with a GMO and setting out details of the operation of the three committees established under the GT Act.

Schedule 3 of the Regulations, lists those dealings with a GMO which are notifiable low risk dealings. In accordance with the provisions of subsection 74(2) of the GT Act, the Regulator must be satisfied that notifiable low risk dealings do not involve the intentional release of a GMO into the environment. In addition, the Regulator, in accordance with subsection 74(3) of the GT Act, must also consider certain matters in relation to those regulations which declare a dealing with a GMO to be a notifiable low risk dealing.

In addition, the Regulations:

- prescribe time limits in which the Regulator must consider and decide applications for certification of facilities and accreditation of organisations under the GT Act (proposed Division 3 of Part 3);

- prescribe the terms and conditions of appointment and other obligations of members and expert advisers to Committees and subcommittees established by the GT Act (proposed Division 1 of Part 4, Part 5 and Part 6);

- prescribe procedures for the conduct of meetings and the performance of other functions of Committees established by the GT Act (proposed Divisions 2 and 3 of Part 4; Part 5 and Part 6);

- prescribe information that must be included on the public Record of GMOs and GM Product Dealings in relation to notifiable low risk dealings and GM products (proposed Part 7); and

- enable facilities and organisations that are presently operating under the existing voluntary regulatory system to be certified or accredited under the new regulatory system upon commencement of the relevant sections of the GT Act (proposed Part 8).

Details of the Regulations are set out in the Attachment.

The Regulations commenced on a date coinciding with the commencement of those provisions of the GT Act which commenced under section 2(3) of the GT Act, ie. six months after the GT Act received Royal Assent, if not proclaimed to commence earlier.

A copy of the Regulation Impact Statement is attached.

ATTACHMENT

GENE TECHNOLOGY REGULATIONS 2001

NOTES ON REGULATIONS

PART 1 PRELIMINARY

Regulation 1 Name of Regulations

Regulation 1 provides that the Regulations may be cited as the Gene Technology Regulations 2001.

Regulation 2 Commencement

Regulation 2 provides for the commencement of the Regulations on the date of commencement of provisions of the *Gene Technology Act 2000* (GT Act*)* to which subsection 2(3) apply.

Regulation 3 Definitions

Regulation 3 clarifies that the definitions used in the Regulations have the same meaning as those used in the GT Act. This Regulation also sets out other definitions that are not used in the Act but are used in the Regulations. For example, the terms "animal" and "physical containment level".

Certain words and expressions commonly used in Commonwealth legislation and in these Regulations have, unless the contrary is indicated, the meaning given by the *Acts Interpretation Act 1901*.

PART 2 INTERPRETATION AND GENERAL OPERATION

Regulation 4 Techniques not constituting gene technology

Regulation 4 clarifies that cloning (somatic cell nuclear transfer) is not caught within the definition of 'gene technology' as defined in the GT Act, provided that the somatic cell nuclear transfer does not involve genetically modified material. However, while cloning does not fall within this definition of gene technology (and as such is not intended to be subject to the regulatory scheme for GMOs), the cloning of human beings is expressly prohibited under section 192B of the GT Act.

Regulation 5 Organisms that are not genetically modified organisms

Regulation 5, supported by Schedule 1, excludes a number of organisms from the definition of 'genetically modified organism'.

The definition of 'genetically modified organism' in the GT Act was intentionally cast very broadly to ensure that the definition did not become outdated and ineffectual in response to rapidly changing technology.

As the definition is particularly broad it potentially encompasses things that were never intended to be regulated under this regulatory scheme. For example, organisms that naturally exchange genetic material.

The purpose of this Regulation is to remove from the scheme those types of organisms that are not intended to be regulated under the scheme. In summary, the organisms excluded from the scheme are organisms that:

- have been exempt or excluded from the voluntary Genetic Manipulation Advisory Committee (GMAC) system of controls on GMOs for many years (some since the late 1970s); and/or

- exchange genetic material in nature, and as such do not pose any unique biosafety risks to the environment or human health and safety; and/or

- are commonly used in biological research; and/or

- have a very long history of usage in Australia and overseas.

Following is a list of the organisms that are not considered to be GMOs for the purpose of this regulatory scheme (as detailed in Schedule 1), including some examples of such organisms and the rationale for prescribing them as not being GMOs for the purposes of the legislation.

- a mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species);

It is possible to effect changes to an organism by, for example, applying chemicals rather than by inserting or deleting a gene in the organism (gene technology). For example, wheat produced by treating cells of the wheat plant with a chemical that causes random mutations (heritable genetic changes) in the DNA of the cells. This technique has been used for many years to produce new varieties of plants. Organisms resulting from such technology are not considered to be GMOs for the purposes of the legislation because the process mimics natural mutation processes and the organisms have not had genes inserted or deleted by virtue of gene technology.

- a recombinant organism formed by integration into chromosomal or extrachromosomal DNA sequences of a genetic element that occurs naturally in the species concerned and moves sporadically between genome sites;

Certain species contain naturally occurring pieces of DNA that may spontaneously move within the DNA of that organism. When these pieces of DNA move, they may cause changes in the characteristics of that organism.

The modified organism that results is not considered a GMO because the process is one that occurs in nature.

- an organism that results from the fusion of 2 animal cells and is unable to form a viable whole animal;

For example, hybridomas created to produce monoclonal antibodies are cultured cells, growing in a petri dish, that have resulted from fusing an antibody-producing cell with another cell. The cell culture is used in the laboratory to produce a particular antibody that can be used in research. There is no possibility of the cells surviving outside the petri dish.

- an organism that results from protoplast fusion involving only non-pathogenic bacteria or non-pathogenic yeast;

For example, an organism that results when cells from two strains of yeast (that are known not to cause disease) are fused together after their cell walls have been removed These methods are standard techniques that have been used for many years by microbiologists to produce new bacteria or yeast that do not cause disease.

- a plant formed by embryo rescue, *in vitro* fertilisation, zygote implantation or protoplast fusion.

These methods are standard techniques that have been used for many years by plant breeders to produce new varieties of plants.

- an organism that results from an exchange of DNA if the donor species is also the host species and the vector DNA does not contain any heterologous DNA.

Certain organisms contain naturally occurring pieces of DNA that spontaneously move around within the DNA of that organism (without human intervention).For example, in nature, genetic exchange can occur between bacteria belonging to the same Salmonella species. Organisms that result from exchange of DNA within the same species (and where no genetic material from any other species is introduced) are not, therefore considered to be GMOs for the purposes of the regulatory scheme.

- an organism that results from an exchange of DNA between the donor species and the host species if:

(a) such exchange can occur by naturally occurring processes; and

(b) the donor species and the host species are both mentioned in the same group in Part 2 of the Schedule; and

(c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.

Transfer of genes between different bacterial species occurs commonly in nature. Part 2 of Schedule 3 lists groups of species that are known to exchange genetic information under natural conditions. In order to be exempt, the exchange of DNA must only occur between members of any one group and the vector used must not contain DNA from species outside the same group.

PART 3 DEALINGS WITH GMOs

Division 1 Licensing system

Regulation 6 Dealings exempt from licensing

Regulation 6, supported by Schedule 2, describes those dealings with GMOs that are exempt from the regulatory scheme. Unlike Regulation 5, that describes organisms that are not GMOs for the purposes of the legislation, this Regulation describes dealings with organisms that are GMOs (that is, they are organisms that have been modified by techniques of gene technology), but that are exempt from the scheme on the basis of negligible biosafety risk.

The exempt dealings with GMOs detailed in Schedule 2 are dealings with GMOs that have been assessed over many years by the Genetic Manipulation Advisory Committee (GMAC) as presenting negligible biosafety risks to public health and safety, including occupational health and safety, or to the environment.

As an additional precaution, the Regulation also provides that exempt dealings with GMOs:

- must not involve an intentional release of the GMO into the environment; and

- must be conducted in accordance the requirements of Australian Standard AS/NZS; 2243.3.1995 (Safety in laboratories: microbiology) for Physical Containment Level 1.

In addition, accredited organisations undertaking exempt dealings with GMOs are required to seek advice from their Institutional Biosafety Committee (to ensure that the work has not been mis-classified as exempt) and to keep a record of the exempt dealings. These requirements will be imposed by the Regulator as a condition of the accreditation of the organisation.

Subregulation (2) clarifies that a dealing with a GMO that is exempt does not include performing additional genetic modifications. That is, someone may deal with an exempt GMO (for example, use it, possess it etc), but they may not undertake any further genetic modifications on the GMO. If they wish to do so, they must apply for a licence from the Regulator.

The note included in the Regulations clarifies that dealings with GMOs that are exempt under the GT Act are not exempt from any other Commonwealth or State legislation that may also have application.

Part 1 of Schedule 2 describes 6 kinds of exempt dealings:

- dealings with certain gene knock-out mice (where no advantage is conferred on the adult animal);

Gene knock-out mice are mice that have genes removed from their DNA (or 'knocked out' of their DNA) so that the effects of the loss of the gene may be studied.

An important limitation on this exemption is that in order to be exempt, the removal of genes from the mouse must not be able to give rise to an advantage in the modified adult mouse over wild type unmodified mice. If it is possible that an advantage may be conferred on the mouse as a result of the deletion of the gene then the work is not exempt.

- dealings with animals where naked recombinant nucleic acid has been introduced into the animal's somatic cells provided the introduced nucleic acid is not capable of giving rise to infectious agents;

The introduction of naked recombinant nucleic acid into an animal's somatic cells does not involve manipulation of the animal's genome. The significance of this is that if the genome has not been manipulated then the modified material will not be present in the genome of subsequent generations.

An example of this technique is using strands of DNA as vaccines to vaccinate animals against disease. This is a technique that has the potential to be safer than current non-GMO vaccines which use live, weakened strains of an organism (eg the polio vaccine).

- dealings with animals into which genetically modified somatic cells have been introduced unless the cells are capable of giving rise to recombinant infectious agents or contain viral sequences that could recombine with, or be complemented by, genomes of superinfecting viruses;

The risks posed by dealings with animals into which genetically modified somatic cells are introduced are minimal because the modification does not involve any changes to the animals genome (and, as such, the modified material will not be present in the genomes of subsequent generations). Recognising that there may be risks if the cells introduced into the animal are capable of giving rise to infectious agents or contain viral sequences, the exemption only applies where the cells are incapable of giving rise to infectious agents and do not contain viral sequences that could recombine with, or be complemented by, genomes of superinfecting viruses.

- certain dealings involving approved host/vector systems (Schedule 2, Part 2 identifies different types of approved host/vector systems) provided that the donor DNA is not potentially harmful (for example, as the result of it being an oncogene or coding for toxins);

A host/vector system is a technique for introducing a foreign gene or sequence into an organism. For example, in order to undertake a study of the function of a particular gene, it may be desirable to propagate the gene a number of times and then study it in an organism. In a host/vector system, a transferring agent, for example a virus (the vector), is used to carry a strand of foreign DNA into an organism, for example cultured insect cells (the host).

The Regulations contain a restricted list of combinations of vectors and hosts that have been studied and are considered to offer a safe level of biological containment (approved host/vector systems). This means that it is very difficult for the foreign DNA to spread outside the host/vector system or the resulting GMO (the organism with foreign DNA in it), and unlikely that the GMO could survive outside a laboratory.

While the use of such host/vector systems minimises risks, the Regulations also require that other criteria are met in order for the work to be exempt. For example, in addition to using an approved host vector system, an exempt dealing must not use donor DNA that is an oncogene (a cancer causing gene), is derived from a microorganisms capable of causing disease in humans, animals or plants, or codes for toxin products (may be toxic to animals, plants or humans). If the donor DNA is potentially unsafe because of any of these factors, then the work is not exempt and must not proceed without approval from the Regulator.

- dealings involving shot-gun cloning of mammalian DNA in an approved host/vector system.

Shot-gun cloning is a type of dealing involving pieces of DNA. It is used in research to speed up the process of mapping large genetic sequences. Large genetic sequences can be determined quickly by shot-gun cloning by:

- *breaking the long DNA sequences down into small pieces;*

- *putting small pieces of DNA into vectors;*

- *determining the sequence of the small bits of DNA; and*

- *using computer programs to reassemble all the small sequences into the large sequence.*

These experiments are regarded as posing negligible risk because of:

(a) the confidence in the biological containment provided by the approved host/vector systems;

(b) the observation that interactions between mammalian DNA and many microbes have been occurring throughout evolution;

(c) the widespread and safe use of shot-gun cloning of mammalian DNA that has occurred in laboratories world-wide; and

(d) the understanding that DNA encoding a mammalian oncogene would only pose a possible hazard to researchers if the DNA was injected or introduced into the body (and would pose no hazard to the broader community).

Regulation 7 Application for licence – prescribed information

Regulation 7, supported by Schedule 4, prescribes information that must be contained in an application for a licence to undertake a dealing with a GMO. The Regulation sets out different information requirements depending on whether the proposed dealings with the GMO involve the intentional release of the GMO into the environment, or do not involve such release.

Schedule 4 sets out the minimum information to be provided by applicants in respect of applications for a licence to the Regulator. The Regulator may also request any additional information that is necessary to assist the Regulator's consideration of the application.

The Regulation requires that information provided to the Regulator in the course of applying for a licence must be as comprehensive as existing scientific knowledge permits at the time of

application. The application must include all known information, supported by relevant data and references, about any impacts of the GMO on human health and safety and/or the environment.

Where comprehensive information is not supplied at the time of application, an applicant must identify all the gaps in the information which is supplied and provided with the application, to allow for an in-depth analysis of the risks posed by the absence of that information in the application.

This Regulation ensures that, as far as possible, in considering an application, the Regulator is provided with comprehensive information and that the absence of information is also taken into account by the Regulator when assessing the possible risks to the health and safety of people or the environment. The Regulator may always ask for more information if, he or she believes this is required by virtue of section 42 of the GT Act.

Regulation 8 Time Limits for deciding an application

Regulation 8 establishes the time frames within which the Regulator must issue, or refuse to issue, a licence authorising specified dealings with one or more specified GMOs.

The timeframes in which such decisions must be made are:

- 90 days after the day of receipt of an application that does not involve intentional release of a GMO into the environment; and

- 170 days after the day of receipt of an application that does involve intentional release of a GMO into the environment.

The Regulation also provides for circumstances under which the minimum time frames for considering the application will be suspended, and the permitted 90 days and 170 days will therefore be adjusted upward as necessary.

The time for considering the application will be suspended when the Regulator:

- is waiting for further information which has been requested in writing from the applicant; or

- has called for a public hearing; or

- is considering a request from the applicant that information provided by the applicant is confidential commercial information; or

- is seeking advice from the Gene Technology Ethics Committee (GTEC) on a relevant issue.

Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted when calculating the proposed permitted time frames.

In considering an application for a licence for dealings involving the intentional release of a GMO into the environment, the Regulator must seek advice on risk assessment and risk management plans from the States, the Gene Technology Technical Advisory Committee (GTTAC), each Commonwealth agency and authority prescribed in Regulation 9, the Environment Minister and any local council that the Regulator considers appropriate. Subregulation 8(3) provides that the Regulator may specify a reasonable time within which such organisations must provide advice to the Regulator. The GT Act provides that the Regulator must give such organisations a minimum of 30 days to respond to a request for advice, however, the Regulator, may in a notice in writing specify a longer period of time.

If a body listed in the previous paragraph does not provide their advice within the specified time, then the Regulator may proceed with his/her consideration of the application, without such

advice. It should be noted that the time for consideration of an application is not suspended while advice is being sought from such organisations.

The Regulator may also refer an issue raised in an application to GTEC for consideration. The Regulator may specify a time period within which such advice is required and for the duration of that period, the timeframe for consideration of the application is suspended. There is no minimum time limit prescribed in this instance.

Regulation 9 Prescribed authorities

Regulation 9 prescribes the Commonwealth authorities and agencies with whom it is intended that the Regulator must consult in particular situations.

The Commonwealth authorities and agencies prescribed are:

- the Australia New Zealand Food Authority;
- the Australian Quarantine and Inspection Service;
- the National Health and Medical Research Council;
- the National Industrial Chemical Notification and Assessment Scheme, National Occupational Health and Safety Commission;
- the National Registration Authority for Agricultural and Veterinary Chemicals; and
- the Therapeutic Goods Administration, Department of Health and Aged Care.

If the Regulator receives an application for a licence to undertake dealings involving intentional release of the GMO into the environment, the Regulator must consult these agencies on the application in order to inform the Regulator's preparation of a risk assessment and a risk management plan.

The Regulator must also consult these agencies again when the Regulator has prepared a risk assessment and risk management plan, which will, in effect be the draft decision in relation to the application.

This ensures that the Regulator will be fully advised of any issues and concerns which may exist from as broad a group of interested parties as is reasonably possible, in relation to GMOs and the risks associated with the proposed dealings. The list is not exhaustive and the Regulator may consult with other authorities and agencies as the Regulator considers desirable in deciding any application.

Consultation with the agencies and authorities detailed in this Regulation is in addition to the requirements for public consultation on draft risk assessments and risk management plans prepared by the Regulator. The GT Act provides that before making a decision on an application, the Regulator must publish a notice in the Gazette, in a newspaper circulating generally in all States and on the Regulator's website, inviting public submissions on any risk assessment and risk management plan prepared by the Regulator.

Regulation 10 Risk assessment – matters to be taken into account

Regulation 10 prescribes additional matters that the Regulator must take into consideration in preparing a risk assessment and a risk management plan.

Section 51 of the GT Act sets out a range of matters that the Regulator must take into account in preparing a risk assessment and risk management plan in relation to dealings with a GMO proposed to be authorised by a licence. These matters include:

- risks posed by the dealings including any risks to the health and safety of people or risks to the environment;

- any submissions made by the public in relation to such risks; and

- any advice provided by the States, the Gene Technology Technical Advisory Committee, Commonwealth agencies, the Environment Minister and local councils.

The Regulator must take previous assessments of dealings with GMOs in either Australia or overseas into account. The Regulator must also consider the potential of the GMO to be harmful to other organisms; to adversely affect any ecosystems; to transfer genetic material; to spread or persist in the environment; to have a selective advantage in the environment; or to be toxic, allergenic or pathogenic to other organisms.

In examining the potential of the GMO to have such effects, the Regulator will be looking at the possible impact of the GMO on all organisms including animals, plants and humans.

The Regulation also clarifies that the Regulator must consider potential long term and short term risks when preparing a risk assessment and risk management plan.

Regulation 11 Prescribed conditions of licence

This Regulation flags that the Regulations may, at a future time, include prescribed conditions of licence. At the commencement of these Regulations, no conditions are prescribed. However, sections 63, 64 and 65 of the GT Act do set out standard conditions that apply to all licences granted by the Regulator. The GT Act provides that the Regulator may impose any conditions that the Regulator considers necessary for managing any risks to the health and safety of people or the environment.

Division 2 Notifiable low risk dealings

Regulation 12 Notifiable low risk dealings

Regulation 12, supported by Schedule 3, details those dealings with GMOs that are notifiable low risk dealings. A dealing with a GMO is a notifiable low risk dealing if it is listed in Part 1 of Schedule 3 (provided that the dealing is not also mentioned in Part 2 of Schedule 3) and it does not involve intentional release of a GMO into the environment.

Notifiable low risk dealings with a GMO are ones that:

- do not involve the intentional release of a GMO into the environment; and

- are of minimal risk to the health and safety of people and the environment having regard to:

- whether the GMO is biologically contained so that it is not able to survive or reproduce without human intervention; and

- the potential properties of the GMO as a pathogen or pest and the toxicity of any proteins produced by the GMO.

- the Regulator has also considered whether any conditions are necessary to manage any risks associated with the properties of the GMO.

The conditions required to manage the minimal risks are detailed in Regulation 13.

The notifiable low risk dealings detailed in Schedule 3, have been developed following consideration by the Regulator of the matters detailed above. In addition, the dealings which have been identified as notifiable low risk dealings are based on GMAC Category B activities which have been assessed over time as presenting minimum biosafety risks.

It is important to note that even if a dealing with a GMO falls within Part 1 of Schedule 3, it will not be a notifiable low risk dealing if it also falls within Part 2 of Schedule 3. If the proposed dealing falls within Part 2 of Schedule 3, a licence must be obtained from the Regulator, before the dealing can be conducted

Following is a summary of the types of dealings with GMOs that are notifiable low risk dealings (subject to them not also falling within Part 2 of Schedule 3) and some examples of the types of dealings.

- Any dealing involving whole animals (including non-vertebrates) that:

(i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and

(ii) does not involve gene-knockout mice.

For example, production of a laboratory mouse that has an altered form of one of its genes. Researchers can study the characteristics of the mouse to learn about the function of the gene that has been altered.

The dealings with whole animals described above are limited by Part 2 of Schedule 3. Dealings with whole animals that are higher risk (because of the type of genetic modification applied) are not notifiable low risk dealings. Part 2 of Schedule 3 describes such higher risk GMOs. For example, if a viral vector has been used to produce a transgenic animal that secretes or produces recombinant viral agents then the dealings with the GMO are not notifiable low risk dealings and must be licensed by the Regulator.

In relation to those dealings with whole animals that are low risk (and are not considered to be higher risk by virtue of characteristics described in Part 2 of Schedule 3), conditions must also be complied with to ensure that even the minimal risks can not be realised. For example, Regulation 13 requires that work with whole animals be conducted within a facility certified by the Regulator to be at least PC2 (or otherwise certified to a containment level that the Regulator considers suitable) and appropriate to contain the particular type of animal.

- Any dealing involving a genetically modified flowering plant, if:

(i) the dealing does not involve the plant being grown to flowering stage; or

(ii) for a dealing that does involve the plant being grown to flowering stage:

(A) the plant is male sterile and is unable to set seed; or

(B) if the plant is male sterile and can set seed — all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or

(C) before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed; or

(D) if the plant can be wind-pollinated — all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or

(E) if the plant can be vector-pollinated only — all vents and drains in the facility are screened with mesh or filters that block the escape of viable seed and exclude pollen vectors from the facility;

In combination with Regulation 13 (requirements in relation to notifiable low risk dealings), the effect of this provision is that a person may deal with a genetically modified flowering plant provided the plant is contained within a PC2 facility and, if the plant is grown to flowering stage, additional precautions are undertaken. The additional precautions ensure that seed or pollen do not escape from the PC2 glasshouse.

- Any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 1, if:

(i) the host is incapable of causing disease in human beings, animals, plants or fungi; and

(ii) the vector is incapable of causing disease in human beings, animals, plants or fungi;

For example, production of a genetically modified bacterium that is capable of producing insulin, where the wild-type unmodified bacterium occurs naturally in the human gut and does not cause disease.

Regulation 13 requires that such work must be carried out in laboratories certified to at least PC2 in accordance with procedures designed to prevent the transmission of the organisms outside of the laboratory. Further, in order to be a notifiable low risk dealing, both the hosts and the vectors used in these experiments must be non-pathogenic.

Dealings with these types of GMOs are also limited by Part 2 of Schedule 3. If the dealing, despite falling within this category, also involves, for example, high level expression of toxin genes, then the dealing will not be a notifiable low risk dealing and, if undertaken, must be licensed by the Regulator.

- Any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 1, if, although the host or vector is capable of causing disease in human beings, animals, plants or fungi, the donor DNA is fully characterised and will not increase the virulence of the host or vector;

An example of the use of such technology is scientists studying the basis for pathogenicity in a bacterium such as Clostridium perfringens who wish to study the regulation of a gene which encodes an outer membrane protein believed to play a role in virulence. Because the assay for the presence of such a protein is complex and difficult, a strain is constructed in which this protein is replaced by a harmless protein, whose presence is easily detected. These are called reporter proteins and two examples are the enzyme ß-galactosidase and the coloured protein Green Fluorescent Protein (GFP). The loss of the outer membrane protein decreases the pathogenicity of the strain which is not otherwise affected by the addition of the reporter protein. Experiments such as these are important for investigating the biology of pathogenic microorganisms.

The risks posed by such dealings are minimal as the result of a number of factors. Firstly, the donor DNA used, must be fully characterised. This means that the physical makeup of the DNA has been researched and that an understanding has been obtained about the function of the genes in the DNA. Secondly the work must not involve any factors that may increase risk (these factors are outlined in Part 2 of Schedule 3). Thirdly, the work must be conducted in a laboratory that has been certified by the Regulator as being at least PC2 in order to ensure proper physical containment of the GMO.

- Any dealing involving a host/vector system mentioned in Part 2 of Schedule 1, if the gene inserted:

(i) is a pathogenic determinant; or

(ii) is uncharacterised DNA from a micro-organism that is capable of causing disease in human beings, animals, plants or fungi); or

(iii) is an oncogene.

For example, the use of rat cells to test genes which cause cancer or tumours when the rat cells containing the test gene are grown in petri dishes. There is no risk of the rat cells surviving outside the laboratory and the methods used to insert the genes are recognised as being safe.

Such dealings with GMOs may only be undertaken as notifiable low risk dealings if other risk factors are not also present. Part 2 of Schedule 3, describes such risk factors. If a dealing involves any of the risk factors identified at Part 2 of Schedule 3, then the dealing must not proceed as a notifiable low risk dealing and, if undertaken, must be licensed.

Regulation 13 Requirements in relation to notifiable low risk dealings

Regulation 13 establishes the conditions and requirements that must be complied with by a person proposing to undertake, or who is undertaking, a notifiable low risk dealing.

If a person wishes to undertake a notifiable low risk dealing, they must first consider whether the proposed dealing with the GMO appears in Part 1 of Schedule 3. If they consider that the dealing falls within this Part (and does not also fall within Part 2 of Schedule 3), then the person must prepare detailed information about the proposed dealing with the GMO, in accordance with the Regulator's information requirements as set out in Part 3 of Schedule 3.

Regulation 13 also provides that an Institutional Biosafety Committee (IBC) must assess the information prepared by the person. The purpose of this is to ensure that the person has not incorrectly classified the dealing as a notifiable low risk dealing.

This Regulation further provides that, within 14 days of the IBC's assessment, the IBC must notify the Regulator of the proposed dealing, by giving the Regulator a copy of the information prepared by the person (in accordance with the Regulator's information requirements set out in Part 3 of Schedule 3), together with the IBC's assessment of the information and any other supporting information (also described in Part 3 of Schedule 3).

Once the IBC has written to the person and the project supervisor, advising them that the IBC has notified the Regulator, the notifiable low risk dealings with the GMO may commence. This Regulation further provides that once these preconditions have been met, the person undertaking the notifiable low risk dealing must also comply with certain conditions which assist to ensure that any risks associated with the dealing are not realised.

In summary, this Regulation prescribes that notifiable low risk dealings must:

- be conducted within a contained facility certified to at least PC2 and of appropriate design for containing the type of GMO proposed (or otherwise certified by the Regulator as being suitable for containing the particular GMO); and

- be properly supervised (for example by the accredited organisation within which the work is conducted) and a record of the details of the dealings retained; and

- only be transported in accordance with guidelines issued by the Regulator; and

- if the dealing involves organisms that may produce disease in humans, be conducted in accordance with vaccination requirements set out in the Australian Standard AS/NZA2243:3:1995 (Safety in laboratories: microbiology).

Subregulation 13(4) describes the transitional arrangements intended for notifiable low risk dealings. This Regulation provides that if GMAC has issued a notice in respect of the notifiable low risk dealing (and the notifiable low risk dealing is one that is included in Part 1 of Schedule 3 and not in Part 2 of Schedule 3), then the dealing may be conducted for up to 2 years provided that the conditions described in Subregulation 13(2) are complied with.

Division 3 Certification and accreditation

Regulation 14 Regulator to decide certification application within 90 days

Regulation 14 establishes the period during which the Regulator must consider and decide upon an application for certification of a facility. Applications may be made to the Regulator to have facilities certified to a certain containment level.

The Regulator must make a decision on the certification of a facility within 90 days after the application is received. For the purposes of determining the 90 day period, any time during which the Regulator is awaiting a response from an applicant in relation to a request for additional information, is not counted. Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted as part of the 90 days.

Regulation 15 Application for certification – failure to provide section 85 information

Regulation 15 enables the Regulator to refuse to certify a facility that is the subject of an application if the applicant, without reasonable explanation, has not complied with a request for further information within a permitted time.

A refusal to certify a facility is a reviewable decision under the GT Act.

Regulation 16 Regulator to decide accreditation application within 90 days

Regulation 16 establishes the period during which the Regulator must consider and decide upon applications for the accreditation of an organisation under the GT Act.

Accreditation is intended to be a precondition for organisations wishing to undertake notifiable low risk dealings and dealings requiring a licence. It is intended that a key component of accreditation will be establishing to the Regulator's satisfaction, that an organisation has a properly constituted Institutional Biosafety Committee (IBC) or has access to such an IBC. As detailed in relation to Regulation 13, IBCs will play an important role in relation to notifiable low risk dealings by assisting applicants to ensure that a dealing is not inadvertently mis-categorised. The IBC is also required to provide supporting information in support of applications for licences made to the Regulator.

The Regulator must make a decision on the accreditation of an organisation within 90 days of receipt of the application. For the purposes of determining the 90 day period, any time during which the Regulator is awaiting a response from the applicant in relation to a request for additional information, is not counted. Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted as part of the 90 days.

Regulation 17 Application for accreditation – failure to provide section 93 information

Regulation 17 enables the Regulator to refuse to accredit an organisation, if the applicant, without reasonable explanation, fails to provide to the Regulator, within a permitted time period, the information which was requested by the Regulator.

PART 4 GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

Division 1 Conditions of Appointment

Regulation 18 GTTAC members and advisers – term of appointment

Regulation 18 provides for the appointment, by the Minister, of members and expert advisers to the Gene Technology Technical Advisory Committee (GTTAC) for a term of three years, or a lesser period if specified in the instrument of appointment. Members and expert advisers may be reappointed for a further term or terms.

The term of three years was chosen because it balances the interests of the committee, allowing for the development of expertise and corporate knowledge, with the interests of the committee in periodically incorporating new expertise and new ideas to assist it to continue to be relevant in its continually changing environment. It is anticipated that change of membership will be staggered to ensure that a complete turnover of members is avoided every three years. This will reduce the risk of a substantial periodic loss of corporate knowledge and expertise.

Regulation 19 GTTAC members and advisers - resignation

Regulation 19 enables members and expert advisers of GTTAC to resign at any time by advising the Minister in writing of their resignation.

Regulation 20 GTTAC members – disclosure of interests

Regulation 20 provides that before a person is appointed as a member of GTTAC, the person must have provided, to the Minister, a declaration setting out all direct or indirect interests, pecuniary or otherwise, and other possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of GTTAC.

A member who has been appointed and, who then becomes aware of having a direct or indirect interest, including a possible conflict of interest, in a matter about to be discussed at a meeting of GTTAC, must without delay, disclose the interest at or before the meeting at which the matter may be discussed.

A member who discloses such an interest must not be present during any deliberations of GTTAC on the particular matter except to provide information as requested by GTTAC. This provision recognises that despite having an interest, the member may still have other valuable information to contribute to the Committee. The member must not, however, take part in any decision making process of the GTTAC about the matter. Further, the minutes of the meeting must record that the disclosure was made.

This Regulation is designed to ensure that the deliberations of members of GTTAC are not affected, or perceived to be affected, by the personal or other interests of one or more members.

Regulation 21 GTTAC members and advisers – termination of appointment

Regulation 21 sets out the circumstances in which the Minister may terminate the appointment of a GTTAC member or expert adviser. Both members and expert advisers may have their appointment terminated for physical or mental incapacity, or for misbehaviour, which includes failure to disclose an interest.

The GT Act provides that the Chairperson is appointed by the Minister with the agreement of a majority of jurisdictions (jurisdiction is defined in the GT Act). The Regulation, therefore clarifies that the termination of appointment of the Chairperson must also be with the agreement of a majority of jurisdictions. The appointment of any member (other than the Chair) or expert adviser, may be terminated on the initiative of the Minister alone. This is consistent with the fact that the Minister may appoint other members of the Committee and expert advisers without the agreement of the majority of the jurisdictions.

The Minister must terminate the appointment of a member, if that member becomes bankrupt, enters into an arrangement with his creditors, or fails to fulfil his obligations as a member of GTTAC to provide advice on the request of the Regulator or the Ministerial Council. If a member fails to attend GTTAC for three consecutive attendance days without being granted leave of absence under Regulation 22, the Minister must terminate their appointment. The Minister does not have discretion in these matters and must terminate the appointments if these events occur. The termination of appointment of members of GTTAC is subject to section 27A of the *Administrative Appeals Tribunal Act 1975* and the Code of Practice which was set up to facilitate the review of any reviewable decision in circumstances where a person's interests are affected by a notice of termination of appointment.

Regulation 22 GTTAC members – leave of absence

Regulation 22 provides that leave of absence may be granted to the Chairperson of GTTAC by the Minister. The Chairperson may grant leave of absence to any other members.

Leave of absence which is properly granted in accordance with this Regulation is intended to ensure that the Chairperson and any member who takes official leave will not be in breach of the conditions of their appointment and risk the possibility of their appointment being terminated for absence.

Regulation 23 Expert advisers – disclosure of interests

Regulation 23 ensures that before a person may be appointed as an expert adviser to GTTAC, the person must have provided to the Minister, a declaration, setting out all direct or indirect interests, pecuniary or otherwise, and possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of GTTAC.

An expert adviser, who then becomes aware of having a direct or indirect interest, including a possible conflict of interest, in a matter about to be discussed at a meeting of GTTAC, must without delay, disclose the interest at or before the meeting at which the matter may be discussed.

A disclosure made by an expert adviser must be recorded in the minutes of the meeting. This ensures that the deliberations of GTTAC are not affected by the personal interests of any expert advisers.

Division 2 Committee Procedures

Regulation 24 Committee procedures generally

Regulation 24 provides additional detail about how GTTAC must perform its functions.

Under the Regulations, GTTAC must act in accordance with these Regulations, and as informally and as quickly as due and proper consideration of the issues before the Committee permits.

GTTAC may also obtain further information in any way that it considers appropriate. In obtaining information, the Committee must observe any directions given in a request from the Regulator or the Ministerial Council. For example, the Ministerial Council may consider it important that consultation be undertaken in a particular way or with a particularly broad group of stakeholders.

In such a circumstance, the Ministerial Council would include in their request for advice from the Committee, a requirement that such consultation be undertaken.

Regulation 25 Committee meetings

Regulation 25 provides some basic parameters to GTTAC in terms of how, when and how often it must meet. It authorises the Chairperson of GTTAC to direct the Committee to hold meetings. Notices of meetings must be sent to GTTAC by the Chairperson in writing and specify the time, place and matters for consideration. The Chairperson may organise meetings by video conference or teleconference if the Chairperson thinks fit.

In order to impose some discipline on the Committee (in terms of number of face-to-face meetings) and to enable accountability (including in terms of resources allocated to support the work of the Committee), it is intended that at the beginning of each year the Chairperson and the Regulator will agree on the maximum number of face-to-face meetings that will be held that year. Work proposals and work plans will be prepared based on the proposed meeting timetable. This will enable members to plan their calendars so as to be available for meetings and minimise the need for a member to apply for leave or be absent. The Committee may not meet face-to-face more times than is agreed (or at all if there is no agreement).

If the agreed number of face-to-face meetings is not adequate to enable the Committee to properly consider the issues before it, the Chair and the Regulator may agree that additional meetings be held (beyond those agreed in the workplan). The Chair may also direct the Committee to hold meetings and resolve issues by teleconference or videoconference or to meet out of session. 'Out of session' is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone or any other method that does not involve simultaneous meeting and voting by GTTAC.

This Regulation will ensure that the Regulator's responsibility for managing the Office of Gene Technology Regulator is balanced with the activities of GTTAC.

Regulation 26 Presiding member

Regulation 26 ensures that the Chairperson must preside at all GTTAC meetings, or appoint another member to preside. A member who is appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any of the other committees established under the provisions of the GT Act. This is intended to ensure total independence of the Chairperson and prevent the possibility of cross interests of members improperly affecting the deliberations of the Committee. It is, intended that, when the Chairperson is present at a meeting of GTTAC, the Chairperson will, in usual circumstances, be the presiding member.

If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chair's absence. This provision is intended to ensure that the business of GTTAC will not be hindered or stopped by the temporary non-availability of the appointed Chairperson.

Regulation 27 Quorum

Regulation 27 establishes the quorum for a meeting of the GTTAC. The GT Act provides that the Minister is to appoint up to 20 members to GTTAC. A quorum will exist if half of those members who have been appointed are present at the meeting.

Regulation 28 Voting

Regulation 28 describes the requirements for a valid vote of GTTAC. A decision of GTTAC will be carried by a majority of the members present and voting for the motion. If the Chairperson nominates a member to preside, or if a member has been appointed to preside at the meeting in

the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise, the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

Regulation 29 Records and Reports

Regulation 29 sets out the procedures for the maintenance of records of proceedings and resolutions. A record of all proceedings must be kept by GTTAC and a copy of every resolution passed by GTTAC must be provided to the Regulator.

The Regulator must keep copies of all resolutions of the Committee and make them available to the public, for example, by posting them on the Regulator's website or by including them in quarterly reports to be issued by the Regulator in accordance with the GT Act. Information that the Regulator considers is confidential commercial information is intended to be excluded from public access.

The Regulation seeks to ensure that the activities of GTTAC are made known to the Regulator and all decisions of GTTAC are available to the public, while safeguarding legitimate confidential commercial information. It also ensures that GTTAC must report on its activities to the Regulator, thus enabling the Regulator to provide comprehensive periodic reports.

Division 2 Subcommittees

Regulation 30 Operation of subcommittees

Regulation 30 establishes the procedures and rules for the operation of subcommittees of GTTAC established under section 105 of the GT Act.

This Regulation establishes:

a) the procedures under which a subcommittee must operate;

b) the arrangements for the conduct of a subcommittee meeting;

c) the requirement that the Chairperson must preside at a meeting (or if absent appoint a member to preside); and

d) the procedures for voting at a subcommittee meeting.

The procedures for subcommittees reflect, as far as possible, the procedures for GTTAC. In this regard:

- A subcommittee must act in accordance with these Regulations, as informally and as quickly as due and proper consideration of the issues put before it permits. The subcommittee may obtain further information in any way that it considers appropriate. The scope of the information which may be sought will be limited by any directions issued by the Regulator or Ministerial Council. It is intended that such directions will specify the extent to which or the manner in which such information may be obtained.

This Regulation ensures that any subcommittee functions properly in accordance with the provisions of the GT Act and these Regulations, efficiently and consistently with GTTAC procedures while safeguarding the interests of applicants, the GTTAC and the subcommittee.

- The Chairperson of the subcommittee may direct the subcommittee to hold meetings. As is the case for GTTAC, it is intended that the Chair of the subcommittee will agree with the Regulator, at the beginning of the year, a maximum number of face-to-face meetings to be held that year. Details of such meetings will be notified to the subcommittee by the Chairperson in writing and will specify the time, place and matters for consideration. Meetings may be

conducted by means of video conference or teleconference if the Chairperson considers such forums to be appropriate and efficient. Any such meetings held by videoconference and teleconference may discuss and resolve issues as if such meetings were held as face-to-face meetings. The Chairperson may also arrange meetings out of session. 'Out of session' is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone of any other method that does not involve simultaneous meeting and voting of the members.

- The Chairperson must preside at all subcommittee meetings or appoint a member to preside. A member who is appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any other committees established under the provisions of the GT Act. This ensures the independence of the position of the Chairperson of the subcommittees and prevents the possibility of cross interests from other committees improperly affecting the deliberations of the other committee concerned. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chairperson's absence. This ensures that the business of the subcommittee will not be hindered or stopped by the temporary non-availability of the Chairperson.

- A decision of the subcommittee will be carried by a majority of the members present and voting for the motion. If the Chairperson has nominated a member to preside, or if a member has been appointed to preside over the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

- A quorum exists if half of the members of the subcommittee are present

- The subcommittees must keep records of their proceedings and must give a copy of each resolution passed by them to GTTAC. This is intended to ensure that GTTAC is kept up to date on the activities and resolutions of the subcommittees (if any).

PART 5 GENE TECHNOLOGY COMMUNITY CONSULTATIVE COMMITTEE

Part 5 of the Regulations (Regulations 31 to 33 inclusive) prescribes those issues which apply to the Gene Technology Community Consultative Committee (GTCCC).

Regulations 31, 32 and 33 mirror as far as possible, in respect of GTCCC, the conditions which apply to the GTTAC, as set out in Regulations 18-23 inclusive, and establish the conditions of appointment to GTCCC, committee procedures and function and operation of any subcommittees which may be established. The GT Act does not provide for the appointment of expert advisers to GTCCC.

Regulation 31 GTCCC – conditions of appointment

Regulation 31 operates as follows:

- Members of GTCCC are appointed by the Minister, for a term of three years or a lesser period if specified in the instrument of appointment. Members may be reappointed for a further term or terms. The term of three years was chosen because it balances the interests of the committee, allowing for the development of expertise and corporate knowledge, with the interests of the committee in periodically incorporating new expertise and new ideas to assist the committee to continue to be relevant in its continually changing environment. It is anticipated that change of membership will be staggered to ensure that a complete turnover of members is avoided every three years. This reduces the risk of a substantial periodic loss of corporate knowledge and expertise.

- Members of the GTCCC may resign at any time by advising the Minister in writing of their resignation.

- Before a person may be appointed as a member of GTCCC, the person must have provided to the Minister, a declaration, setting out all direct or indirect interests, pecuniary or otherwise, and other possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of GTCCC. A member after appointment, who then becomes aware of having a direct or indirect interest, including a possible conflict of interest, in a matter about to be discussed at a meeting of GTCCC, must without delay, disclose the interest at or before the meeting at which the matter may be discussed. A member who discloses such an interest must not be present during any deliberations of GTCCC on the particular matter except to provide information as requested by GTCCC. This provision recognises that despite having an interest, the member may still have other valuable information to contribute to the Committee. That member, however, must not take part in any decision making process of GTCCC about the matter. Further, the minutes of the meeting must record that the disclosure was made. These requirements ensure that the deliberations of GTCCC are not affected, or perceived to be affected, by personal interests of one or more members.

- The Minister may terminate the appointment of a member of the GTCCC. A member may have their appointment terminated for misbehaviour, which includes failure to disclose an interest, or for physical or mental incapacity. The GT Act provides that the Chairperson is appointed by the Minister with the agreement of a majority of jurisdictions (jurisdiction is defined in the GT Act). This Regulation, therefore clarifies that the termination of appointment of the Chairperson must also be with the agreement of a majority of jurisdictions. The appointment of any member other than the Chairperson, may be terminated on the initiative of the Minister alone. The Minister must terminate the appointment of a member if that member becomes bankrupt, enters into an arrangement with his creditors, or fails to fulfil his or her obligations as a member of the GTCCC to provide advice on the request of the Regulator or the Ministerial Council. If a member fails to attend the GTCCC for three consecutive attendance days without being granted leave of absence under Regulation 22, the Minister must terminate their appointment. The Minister does not have discretion in these matters and must terminate the appointments if these events occur.

- The termination of appointment of members of GTCCC is subject to section 27A of the *Administrative Appeals Tribunal Act 1975* and the Code of Practice which was set up to facilitate the review of any reviewable decision in circumstances where a person's interests are affected by a notice of termination of appointment.

- Leave of absence may be granted to the Chairperson of the GTCCC by the Minister. The Chairperson may grant leave to any other member. Leave of absence which is properly granted in accordance with this Regulation ensures that the Chairperson and any member who takes official leave will not be in breach of the conditions of their appointment and risk the possibility of their appointment being terminated for absence.

Regulation 32 GTCCC – Consultative Committee procedures

Regulation 32 establishes the committee procedures of GTCCC consistently, as far as possible, with the procedure for operation of GTTAC as set out in Regulations 24-29 inclusive.

The intended operation of Regulation 32 is as follows:

- GTCCC must act in accordance with these Regulations and, as informally and as quickly as due and proper consideration of the issues before the committee permits. GTCCC may obtain further information in any way that it considers appropriate. In obtaining information, the Committee must observe any directions given in a request from the Regulator or the Ministerial Council. For example, the Ministerial Council may consider it important that consultation be undertaken in a particular way or with a particularly broad group of stakeholders. In such a

circumstance, the Ministerial Council would include in their request for advice from the Committee, a requirement that such consultation be undertaken.

- The Chairperson of GTCCC may direct GTCCC to hold meetings. Notices of meetings must be sent to GTCCC by the Chairperson, in writing and specify the time, place and matters for consideration. The Chairperson may organise meetings by video conference or teleconference if the Chairperson thinks fit. In order to impose some discipline on the Committee (in terms of number of face-to-face meetings) and to enable accountability (including in terms of resources allocated to support the work of the Committee), it is intended that at the beginning of each year the Chairperson and the Regulator will agree on the maximum number of face-to-face meetings that will be held that year. Work proposals and work plans will be prepared based on the proposed meeting timetable. This enables members to plan their calendars so as to be available for meetings and minimise the need for a member to apply for leave or be absent. The Committee may not meet face-to-face more times than is agreed (or at all if there is no agreement). If the agreed number of face-to-face meetings is not adequate to enable the Committee to properly consider the issues before it, the Chair and the Regulator may agree that additional meetings be held (beyond those agreed in the workplan).

- The Chair may also direct the Committee to hold meetings and resolve issues by teleconference or videoconference or to meet out of session. 'Out of session' is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone or any other method that does not involve simultaneous meeting and voting by GTCCC.

- This Regulation ensures that the Regulator's responsibility for managing the Office of the Gene Technology Regulator is balanced with the activities of the GTCCC.

- The Chairperson must preside at all GTCCC meetings or appoint another member to preside. Any member who is so appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any of the other Committees established under the provisions of the GT Act. This ensures total independence of the Chairperson and prevents the possibility of cross interests of members improperly affecting the deliberations of the Committee. It is intended that when the Chairperson is present at a meeting of GTCCC, the Chairperson will, in usual circumstances, be the presiding member. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chair's absence. This provision ensures that the business of the GTCCC will not be hindered or stopped by the temporary non-availability of the appointed Chairperson.

- A quorum for a meeting of GTCCC exists if half of the members who have been appointed are present at the meeting. The GT Act provides that the Minister shall appoint up to 12 members to the GTCCC and one of those members shall be appointed as the Chairperson.

- A decision of GTCCC is carried by a majority of the members present and voting for the motion. If the Chairperson nominates a member to preside, or if a member has been appointed to preside at the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

- A record of all proceedings must be kept by GTCCC and a copy of every resolution passed by the GTCCC must be provided to the Regulator. The Regulator must keep copies of all resolutions of the Committee and make them available to the public, for example by posting them on the Regulator's website or by including them in quarterly reports to be issued by the Regulator in accordance with the GT Act. Resolutions which contain information that the Regulator considers is confidential commercial information is intended to be excluded from public access. This ensures that the activities of the GTCCC are made known to the Regulator and all decisions of the GTCCC are available to the public while safeguarding information that is legitimately confidential commercial information. It also ensures that the GTCCC must report on

its activities to the Regulator, thus enabling the Regulator to provide comprehensive periodic reporting.

Regulation 33 GTCCC – operation of subcommittees

Regulation 33 establishes the procedures and rules for the operation of subcommittees of the GTCCC which may be set up under section 110A of the GT Act.

This Regulation establishes:

a) the procedures under which a subcommittee must operate;

b) the arrangements for the conduct of a subcommittee meeting;

c) the requirement that the Chairperson must preside at a meeting (or if absent, appoint a member to preside); and

d) the procedures for voting at a subcommittee meeting.

The procedures for subcommittees reflect as far as possible, the procedures for GTCCC. In this regard:

- A subcommittee must act in accordance with these Regulations, as informally and as quickly as due and proper consideration of the issues put before it permits. The subcommittee may obtain further information in any way that it considers appropriate. The scope of the information which may be sought will be limited by any directions issued by the Regulator or Ministerial Council. It is intended that such directions will specify the extent to which, or the manner in which, such information may be obtained.

This Regulation ensures that the subcommittee functions properly in accordance with the provisions of the GT Act and these Regulations, efficiently and consistently with GTCCC procedures while safeguarding the interests of the GTCCC and the subcommittee.

- The Chairperson of the subcommittee may direct the subcommittee to hold meetings. As is the case for GTCCC, it is intended that the Chair of the subcommittee will agree with the Regulator, at the beginning of the year, a maximum number of face-to-face meetings to be held that year. Details of such meetings will be notified to the subcommittee by the Chairperson in writing and will specify the time, place and matters for consideration. Meetings may be conducted by means of video conference or teleconference if the Chairperson considers such forums to be appropriate and efficient. Any such meetings held by videoconference and teleconference may discuss and resolve issues as if such meetings were held as face-to-face meetings. The Chairperson may also arrange meetings out of session. 'Out of session' is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone of any other method that does not involve simultaneous meeting and voting of the members.

- The Chairperson must preside at all subcommittee meetings or appoint another member to preside. A member who is appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any other committees established under the provisions of the GT Act. This ensures the independence of the position of the Chairperson of the subcommittees and prevents the possibility of cross interests from other subcommittees from improperly affecting the deliberations of other subcommittees. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chairperson's absence. This ensures that the business of the subcommittee will not be hindered or stopped by the temporary non-availability of the Chairperson.

- A decision of the subcommittee will be carried by a majority of the members present and voting for the motion. If the Chairperson has nominated another member to preside, or if a member has been appointed to preside over the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

- A quorum exists if half of the members of the subcommittee are present.

- The subcommittees must keep records of their proceedings and must give a copy of each resolution passed by them to the GTCCC. This is intended to ensure that the GTCCC is kept up to date on the activities and resolutions of the subcommittees (if any).

PART 6 GENE TECHNOLOGY ETHICS COMMITTEE

Part 6 of the Regulations (Regulations 34 to 36 inclusive) prescribes those issues which relate to the Gene Technology Ethics Committee (GTEC).

Part 6 of the Regulations (Regulations 34 to 36 inclusive) provides for the conditions of appointment and committee procedures for the Gene Technology Ethics Committee (GTEC).

Regulation 34 GTEC – Conditions of appointment

Regulation 34 operates as follows:

- Members and expert advisers to the GTEC are appointed by the Minister, for a term of three years or a lesser period if specified in the instrument of appointment. Members and expert advisers may be reappointed for a further term or terms. The term of three years was chosen because it balances the interests of the committee in allowing for the development of expertise and corporate knowledge, with the interests of the committee in periodically incorporating new expertise and new ideas through new members and advisers, to assist the Committee to continue to be relevant in the continually changing environment. It is anticipated that change of membership will be staggered to ensure that a complete turnover of members or expert advisers is avoided every three years. This will reduce the risk of a substantial periodic loss of corporate knowledge and expertise.

- Members and expert advisers of GTEC may resign at any time by advising the Minister in writing of their resignation.

- Before a person may be appointed as a member of GTEC, the person must have provided to the Minister, a declaration, setting out all direct or indirect interests, pecuniary or otherwise, and other possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of GTEC. A member after appointment, who then becomes aware of having a direct or indirect interest, including possible conflict of interest, in a matter about to be discussed at a meeting of GTEC, must without delay, disclose the interest at or before the meeting at which the matter may be discussed.

- A member who discloses such an interest must not be present during any deliberations of GTEC on the particular matter except to provide information as requested by GTEC. This provision recognises that despite having an interest, the member may still have other valuable information to contribute to the Committee. That member must not, however, take part in any decision making process of GTEC about the matter. Further, the minutes of the meeting must record that the disclosure was made. These requirements will assist to ensure that the deliberations of members of GTEC are not affected, or perceived to be affected, by the personal or other interests of one or more members.

- Before a person may be appointed as an expert adviser to the GTEC, the person must have provided to the Minister, a declaration, setting out all direct or indirect interests, pecuniary or

otherwise, and other possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of the GTEC. An expert adviser, who then becomes aware of having a direct or indirect interest, including a possible conflict of interest, in a matter about to be discussed at a meeting of the GTEC, must, without delay, disclose the interest at or before the meeting at which the matter may be discussed. A disclosure made by an expert adviser must be recorded in the minutes of the meeting. This ensures that the deliberations of the GTEC are not improperly affected by the personal interests of any expert adviser to the GTEC.

- The Minister may terminate the appointment of a GTEC member or expert adviser. Both members and expert advisers may have their appointment terminated for misbehaviour, which includes failure to disclose an interest, or for physical or mental incapacity. The GT Act provides that the Chairperson is appointed by the Minister with the agreement of a majority of jurisdictions (jurisdiction is defined in the GT Act). The Regulation, therefore clarifies that the termination of appointment of the Chairperson must also be with the agreement of a majority of jurisdictions. The appointment of any member or expert adviser, other than the Chairperson, may be terminated on the initiative of the Minister alone. The Minister must terminate the appointment of a member if that member becomes bankrupt, enters into an arrangement with his creditors, or fails to fulfil his obligations as a member of GTEC to provide advice on the request of the Regulator or the Ministerial Council. If a member fails to attend GTEC for three consecutive attendance days without being granted leave of absence, under Regulation 22, the Minister must terminate their appointment. The Minister does not have discretion in these matters and must terminate the appointments if these events occur.

- The termination of appointment of members and expert advisers of GTEC is subject to section 27A of the *Administrative Appeals Tribunal Act 1975* and the Code of Practice which were set up to facilitate the review of any reviewable decision in circumstances where a persons interests are affected by a notice of termination (see Regulation 38).

- Leave of absence may be granted to the Chairperson of GTEC by the Minister. The Chairperson may grant leave to any other member. Leave of absence which is properly granted in accordance with this Regulation ensures that the Chairperson and any member who takes official leave will not be in breach of the conditions of their appointment and the risk the possibility of their appointment being terminated for absence.

Regulation 35 GTEC – Committee procedures

Regulation 35 establishes the committee procedures for GTEC consistently, as far as possible, with the procedures for GTTAC as set out in Regulations 24-29 inclusive.

Regulation 35 operates as follows:

- The GTEC must act in accordance with these Regulations, as informally and as quickly as due and proper consideration of the issues before the Committee permits. The GTEC may obtain further information in any way that it considers appropriate. In obtaining information, the Committee must observe any directions given in a request from the Regulator or the Ministerial Council. For example, the Ministerial Council may consider it important that consultation be undertaken in a particular way or with a particularly broad group of stakeholders. In such a circumstance, the Ministerial Council would include in their request for advice from the Committee, a requirement that such consultation be undertaken.

- The Chairperson of GTEC may direct GTEC to hold meetings. Notices of meetings must be sent to GTEC by the Chairperson, in writing and specify the time, place and matters for consideration. The Chairperson may organise meetings by video conference or teleconference if the Chairperson thinks fit. In order to impose some discipline on the Committee (in terms of number of face-to-face meetings) and to enable accountability (including in terms of resources allocated to support the work of the Committee), it is intended that at the beginning of each year the Chairperson and the Regulator will agree on the maximum number of face-to-face meetings

that will be held that year. Work proposals and work plans will be prepared based on the proposed meeting timetable. This enables members to plan their calendars so as to be available for meetings and minimise the need for a member to apply for leave or be absent. The Committee may not meet face-to-face more times than is agreed (or at all if there is no agreement). If the agreed number of face-to-face meetings is not adequate to enable the Committee to properly consider the issues before it, the Chair and the Regulator may agree that additional meetings be held (beyond those agreed in the workplan). The Chair may also direct the Committee to hold meetings and resolve issues by teleconference or videoconference or to meet out of session. 'Out of session' is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone or any other method that does not involve simultaneous meeting and voting by GTEC.

- This Regulation ensures that the Regulator's responsibility for managing the budget of the Office of the Gene Technology Regulator is balanced with the activities of the GTEC.

- The Chairperson must preside at all GTEC meetings or appoint another member to preside. Any member who is so appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any of the other committees established under the provisions of the GT Act. This ensures total independence of the Chairperson and prevents the possibility of cross interests of members improperly affecting the deliberations of the Committee. It is, intended that, when the Chairperson is present at a meeting of GTEC, the Chairperson will, in usual circumstances, be the presiding member. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chair's absence. This provision ensures that the business of the GTEC will not be hindered or stopped by the temporary non-availability of the appointed Chairperson.

- A quorum for a meeting of GTEC exists if half of those members who have been appointed are present at the meeting. The GT Act provides that the Minister shall appoint up to 12 members to the GTEC.

- A decision of GTEC will be carried by a majority of the members present and voting for the motion. If the Chairperson nominates a member to preside or a member has been appointed to preside over the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

- A record of all proceedings must be kept by the GTEC and a copy of every resolution passed by the GTEC must be provided to the Regulator. The Regulator must keep copies of all resolutions of the Committee and make them available to the public, for example, by posting them on the Regulator's website or by including them in the quarterly reports to be issued by the Regulator in accordance with the GT Act. Resolutions which contain information that the Regulator considers is confidential commercial information will be excluded from public access. This ensures that the activities of GTEC are made known to the Regulator and all decisions of GTEC are available to the public while safeguarding confidential commercial information. It also ensures that GTEC must report on its activities to the Regulator thus enabling the Regulator to provide comprehensive periodic reporting.

Regulation 36 GTEC – operation of subcommittees

Regulation 36 establishes the procedures and rules for the operation of subcommittees of GTEC which may be set up under section 116 of the GT Act.

This Regulation establishes:

a) the procedures under which a subcommittee must operate;

b) the arrangements for the conduct of a subcommittee meeting;

c) the requirement that the Chairperson must preside at a meeting (or if absent, appoint a member to preside); and

d) the procedures for voting at a subcommittee meeting.

The procedures for subcommittees are intended to reflect as far as possible, the procedures for GTEC. In this regard:

- A subcommittee must act in accordance with these Regulations, as informally and as quickly as due and proper consideration of the issues put before it permits. The subcommittee may obtain further information in any way that it considers appropriate. The scope of the information which may be sought will be limited by any directions issued by the Regulator or Ministerial Council. It is intended that such directions will specify the extent to which or the manner in which such information may be obtained.

This Regulation ensures that the subcommittee functions properly in accordance with the provisions of the GT Act and these Regulations, efficiently and consistently with GTEC procedures while safeguarding the interests of applicants, the GTEC and the subcommittee.

- The Chairperson of the subcommittee may direct the subcommittee to hold meetings. As is the case for GTEC, it is intended that the Chair of the subcommittee will agree with the Regulator, at the beginning of the year, a maximum number of face-to-face meetings to be held that year. Details of such meetings will be notified to the subcommittee by the Chairperson in writing and will specify the time, place and matters for consideration. Meetings may be conducted by means of video conference or teleconference if the Chairperson considers such forums to be appropriate and efficient. Any such meetings held by videoconference and teleconference may discuss and resolve issues as if such meetings were held as face-to-face meetings. The Chairperson may also arrange meetings out of session. 'Out of session' is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone of any other method that does not involve simultaneous meeting and voting of the members.

- The Chairperson must preside at all subcommittee meetings or appoint another member to preside. A member who is appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any other committees established under the provisions of the GT Act. This ensures the independence of the position of the Chairperson of the subcommittees and prevents the possibility of cross interests from other subcommittees improperly affecting the deliberations of other subcommittees. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chairperson's absence. This ensures that the business of the subcommittee will not be hindered or stopped by the temporary non-availability of the Chairperson.

- A decision of the subcommittee will be carried by a majority of the members present and voting for the motion. If the Chairperson has nominated a member to preside, or if a member has been appointed to preside over the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

- A quorum exists if half of the members of the subcommittee are present.

- The subcommittees must keep records of their proceedings and must give a copy of each resolution passed by them to the GTEC. This ensures that the GTEC is kept up to date on the activities and resolutions of the subcommittees (if any).

PART 7 MISCELLANEOUS

Regulation 37 Reviewable State decisions

This Regulation anticipates that at some time in the future a list of reviewable State decisions (under section 19 of the GT Act) may be included against this Regulation. However, at the commencement of these Regulations, no such decisions are recorded. This is because at the time of commencement of these Regulations, no State or Territory will have a corresponding State law in place (prescribing that decisions made by the Regulator in performance of a function or power conferred under a corresponding State law are reviewable State decisions).

Regulation 38 Review of Decisions

This is a technical provision which clarifies that if the Minister terminates the appointment of a member, or expert adviser, to a committee, the Minister must give the person a notice of the decision. Information must also be provided about the person's right to have the decision reviewed by the Administrative Appeals Tribunal (AAT). If the member or adviser is dissatisfied with the decision, they may then apply to the AAT to have the decision reviewed by the AAT.

Regulation 39 Record of GMO and GM Product Dealings

Regulation 39 sets out the information that must appear on the Record of GMO and GM Product Dealings (the Record) about notifiable low risk dealings that are notified to the Regulator and GM products. This information is in addition to the information that must be included on the Record in relation to each licence issued by the Regulator, as required by section 138 of the GT Act.

This Regulation provides that the Record must contain the following information about all notifiable low risk dealings that are notified to the Regulator:

- the name of the organisation proposing to undertake the notifiable low risk dealing;

- the kind of notifiable low risk dealing proposed, by reference to the descriptions in Part 1 of Schedule 3; and

- the identifying name given to the proposed undertaking by the organisation (that is, the project title of which the dealing is a part); and

- the date of the notification of the dealing to the Regulator.

This Regulation also sets out the information that is required to be placed on the Record in respect of GM products notified to the Regulator by other regulators such as the Australia New Zealand Food Authority (ANZFA), the National Registration Authority, the Therapeutic Goods Administration and the National Industrial Chemicals Notification and Assessment Scheme.

In respect of such GM products, the Record must include:

- the name of the organisation producing the GM product;

- a description of the GM product by reference to the relevant legislation under which the GM product was approved (for example, whether it is a therapeutic good approved under the *Therapeutic Goods Act 1989*);

- a description of the GM product by reference to its common name as a product, or type or class of product (for example, vegetable oil);

- information about the GM product including:

- the common name and the scientific name of the parent organism involved;

- details of the introduced trait in the GM product; and

- the identity of the introduced gene responsible for conferring the introduced trait.

• the date on which the decision of the other regulator (for example, ANZFA) enabling supply of the GM product in Australia, takes effect; and

• details of any conditions attaching to the decision from the other regulator (for example, labelling conditions in the case of food products).

The Record will be made publicly available (including on the Regulator's website) and will be a comprehensive listing of all GMOs and GM products approved in Australia.

Regulation 40 Inspector identity card

Regulation 40 prescribes additional information that must be included on identity cards carried by inspectors. The additional information on the card (photograph of the investigator's face, date of issue and expiry date) enables the cardholder's identity and authority to act as an Inspector to be readily ascertained and verified by someone to whom it is shown.

PART 8 TRANSITIONAL

Regulation 41 Existing facilities – certification

Regulation 41 is a transitional provision which enables some facilities, that have been approved by the GMAC in the period leading up to the commencement of the GT Act, to be automatically certified for the purposes of the GT Act upon commencement of the GT Act. This enables existing, operational facilities, that already meet certain containment requirements, to continue to operate (for a limited period of time) without having to obtain certification immediately upon commencement of the GT Act.

This Regulation "deems" certain facilities to be certified under section 84 of the GT Act, if prior to the commencement of Part 7 of the GT Act, the GMAC has issued a notice that the facility provides a particular containment level.

The 'deemed' certification will be:

• to the level of containment described in the GMAC notice; and

• effective for up to 2 years from the commencement of the Regulations in the case of facilities certified to PC2 (excluding PC2 Large Scale facilities) and, for up to one year from commencement of the Regulations for all other facilities; and

• subject to sections 86 to 88 of the GT Act. This is intended to ensure that the Regulator can vary, suspend or cancel a 'deemed' certification by notice in writing.

The different time frames for review of deemed certification ensure that different contained facilities are reviewed at rates that reflect the nature of the dealings conducted within them and the level of risk or potential risk posed to public health and environmental safety.

Regulation 42 Existing organisations - accreditation

Regulation 42 provides that organisations currently undertaking dealings with GMOs that receive a notice from the GMAC that they are an accredited organisation, will be "deemed" to be accredited for the purposes of section 92 of the GT Act, upon commencement of the GT Act. This Regulation enables organisations that already meet certain criteria for accreditation (including because they already have an Institutional Biosafety Committee or have access to another

organisation's Institutional Biosafety Committee), to continue to operate without having to obtain accreditation from the Regulator following commencement of the GT Act.

This Regulation also places a number of conditions and limitations on the "deemed" accreditation. Firstly, the "deemed" accreditation is only effective for up to two years (subject to being suspended or cancelled by the Regulator). During the two year transitional period, all organisations must reapply for accreditation in accordance with criteria set down by the Regulator in Guidelines for Accreditation. During the transitional period organisations must comply with the conditions of accreditation detailed in the Regulator's Guidelines for Accreditation made under section 98 of the GT Act.

This Regulation also provides that the Regulator is able to vary, suspend, cancel or impose other conditions in respect of a 'deemed' accreditation, under sections 94 to 96 of the GT Act.

REGULATION IMPACT STATEMENT

FOR THE

GENE TECHNOLOGY REGULATIONS 2001

1 Background

Scope of this Regulation Impact Statement

In early 1999, the Commonwealth Government agreed that:

- a national regulatory system for the control of genetically manipulated organisms (GMOs) and the use of gene technology be developed to replace the existing administrative system;

- the regulatory system would be managed by an independent statutory office holder (the Gene Technology Regulator); and

- the Regulator would derive power from both Commonwealth, State and Territory legislation.

Regulation Impact Statements (RISs) were prepared to guide the development of this policy and the development of the Gene *Technology Act 2000* (the Act) and related Acts. This RIS focuses on the costs and benefits of several components of the proposed regulatory scheme, as reflected in the Gene *Technology Regulations* 2001.

Background information about the current system of controls for gene technology

The Genetic Manipulation Advisory Committee (GMAC) is a non-statutory expert advisory body reporting to the Commonwealth Minister of Health and Aged Care. GMAC's membership includes a wide range of experts in fields such as molecular biology, ecology, plant genetics, agriculture and biosafety engineering.

Since 1975, GMAC (and its predecessors, the Academy of Science Committee on Recombinant DNA and the Recombinant DNA Monitoring Committee) has scrutinised the development and use of novel genetic manipulation techniques in Australia. Each proposal (whether intended as a research and development project or for the commercial release of a GMO) is considered by GMAC on a case by case basis and judged on the individual merits of the application.

To March 2001, GMAC has assessed:

- 5484 proposals for small scale contained work. Small scale genetic manipulation proposals are mostly directed at fundamental and proof of concept research in biology and medicine and are conducted within contained laboratories. Most small scale work is carried out by universities and other research organisations.

- 43 proposals for large scale contained work, such as the production of: hormones, growth factors and vaccines; enzymes for trials in patients with enzyme deficiencies; and enzymes for use in paper pulp production. Most large scale contained work is carried out by commercial organisations (40 of the proposals were from commercial organisations and 3 of the proposals were from universities).

- 259 proposals for field trials of GMOs. Most field trials were for genetically modified plants, with the majority being for cotton or canola. The remaining field trials were for microorganisms such as bacteria, viruses and yeast. Applications for most of the field trials came from commercial companies (44%) or the CSIRO (37%). Of the remaining field trials, 11 % were conducted by universities and 8% by State government agencies.

- 9 applications for general (commercial) release of GMOs**.** Four of these have been approved to date: Bt cotton (which was subsequently regulated by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA); a violet carnation. a carnation with improved vase life; and Roundup Ready cotton. In addition, the NRA has approved, with the advice of GMAC, the release of a genetically modified plant pesticide (in 1989) and a salmonella vaccine (in 1992).

In June 2000, the Federal Government introduced a package of three Bills into Federal Parliament for the regulation of gene technology in Australia - the Gene Technology Bill 2000, the Gene Technology (Consequential Amendments) Bill 2000 and the Gene Technology (Licence Charges) Bill 2000 - to provide more credibility to the oversight of dealings with GMOs. This package was passed by Parliament on 8 December 2001, and will form part of a national regulatory system for GMOs. The objective of the gene technology legislation is to protect the health and safety of people and to protect the environment by identifying risks posed as a result of gene technology and by managing those risks. It does this by creating laws for certain dealings (or activities) with GMOs.

The *Gene Technology Act 2000* provides that regulations can be made to prescribe matters required or permitted to be prescribed by the Act, or matters which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

2. Problem

The Regulation Impact Statement for the Gene Technology Bill 2000 listed a range of potential benefits from the application of gene technology to agriculture, health and the environment that had been identified by supporters of this technology. These benefits included: more efficient use of agricultural and veterinary chemicals, savings in energy inputs to farm production; recovery of degraded land; research into the cause of diseases, improved biopharmaceuticals; and bio-remediation.

However, the very characteristics of gene technology which produce many of the benefits (such as the ability to introduce genes from one species into a different species) are also those that cause concerns in the community. These concerns are related to potential unintended effects on the health of people or the environment, and a number of possible risks were identified in the Regulation Impact Statement to the Gene Technology Bill 2000. These included: higher risks of allergic reactions to genetically modified food; unknown long term consequences that may not be able to be reversed or fixed once the GMO is widely used; and crops so strong that they become weeds or pests.

There are also broader, non-scientific concerns that have been expressed about using gene technology, including ethical, social and moral concerns about the impact of 'humans playing God'.

With these potential risks and benefits in mind, the range of applications for gene technology is changing very rapidly. As also discussed in the Regulation Impact Statement to the Gene Technology Bill 2000, certain GMOs are now being developed which do not fall neatly within the mandate of existing regulators in Australia, such as the Australia New Zealand Food Authority and the Therapeutic Goods Administration. While GMAC has provided advice directly to proponents on these 'gap' GMOs, because of the administrative nature of the GMAC system, governments have had limited capacity to either monitor proponents' compliance with GMAC advice, or to enforce compliance with that advice.

In addition, more GMOs are approaching the commercialisation stage, when producers of the GMOs will be seeking to release the GMO into the environment, either for the purposes of field trials or for commercial release. The GMAC system, which was established a number of years ago, was designed to deal with research into GMOs being conducted in contained facilities, and was not established with a focus on general release.

There is therefore broad community and government concern that the current GMAC system is no longer appropriate. This is because it does not have in place sufficient mechanisms to ensure adequate openness and transparency in its risk assessment and management roles, nor sufficient enforcement capabilities, to adequately address this rapidly developing technology and ensure public health and safety and the protection of the environment.

Lack of confidence (particularly in relation to the assessment of ecological impact and the management of GMOs released into the environment) may also harm the ability of industry to market GMOs and GM products - both domestically and internationally - which have been assessed as safe for release under this system. Indeed, a growing number of Australia's overseas markets - for example, Japan, the European Union, and Sri Lanka - are now demanding that strong regulatory mechanisms be in place to regulate, monitor and record dealings with GMOs.

3. Objective

The objective, as stated in the Gene *Technology Act 2000* (the Act), is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMO).

This objective is to be achieved through a regulatory framework which:

(a) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing costeffective measures to prevent environmental degradation;

(b) provides an efficient and effective system for the application of gene technologies; and

(c) operates in conjunction with other Commonwealth and State regulatory schemes (eg. those that regulate food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods) relevant to GMOs and genetically modified products (GM products).

In essence, the Regulations established under the *Gene Technology Act* 2000 must pursue the object of the Act and must reflect the type of regulatory framework envisaged in the Act. By way of further detail, the government objective with respect to the Regulations (as with the Gene Technology Act) is to:

(a) pursue an efficient and cost effective approach;

(b) continue a science based approach to the assessment of risks but including capacity for formal consideration of broader issues such as ethics;

(c) avoid unnecessary duplication with existing regulators and provide for better coordination of the activities of all regulators involved in the approval of GMOs and GM products;

(d) assist industry by providing a streamlined pathway for seeking and, where appropriate, gaining approval to deal with GMOs and GM products for which safety risks can be managed appropriately;

(e) increase enforceability of the arrangements for managing risk;

(f) achieve greater transparency and accountability; and

(g) be more responsive to stakeholders and community views consistent with the legislation.

4. Options and Impact analysis

This section sets out the various options for each of the key components of the Gene Technology Regulations 2001. As numerous components of the Regulations are examined, for ease of reference, an assessment of the impacts (including the costs, and benefits of each option) has also been included in this section.

In terms of the impacts of the Regulations and the scheme they will support, the groups most likely to be significantly affected by this initiative are:

- government - including Commonwealth, State/Territory and local governments;

- business and researchers - including large, medium and small commercial enterprises, universities and other public research organisations and users of gene technology (including primary producers);

- consumers - those actually using the end product; and

- community members - other members of the general public.

Options and Impact Analysis of key components of the Gene Technology Regulations 2001

(a) Organisms that are not genetically modified organisms

The definition of a GMO (in clause 10 of the *Gene Technology Act 2000)* includes capacity for the regulations to declare that certain organisms are not GMOs for the purposes of the legislation. This provision recognises that the definitions of GMO and gene technology in the Act are cast very broadly, and that the definition of GMO may therefore be interpreted to capture things which were not intended to be regulated under this legislation. Thus this provision provides, as far as reasonably possible, for the scope of a GMO both under the current administrative arrangements and under the legislative arrangements to be analogous.

Option 1: Prescribe a limited class of organisms in the regulations as not being GMOs

To address the problem detailed above, the regulations would set out those organisms that are excluded from the scope of the regulatory system because they have been modified by techniques that do not require regulatory oversight or that fall outside the scope of this regulatory system. These techniques would be excluded from regulatory oversight because they:

- give rise to organisms that can occur in nature, and as such do not pose a particular biosafety risk to the environment or human health and safety; and/or

- are commonly used in biological research; and/or

- have a very long history of usage in Australia and overseas.

For example, some species contain naturally occurring pieces of DNA that can spontaneously move around within the DNA of that organism. When these pieces of DNA move around they may cause changes in the characteristics of that organism, but the modified organism that results is not considered a GMO because the process is one that occurs in nature.

Option 2: Do not prescribe any organisms (as not being GMOs) in the Regulations.

This would mean that organisms such as those detailed at Option 1 would not be set out in the Regulations as being excluded from the regulatory scheme. The effect of this would be that all dealings with such organisms would require licensing, or some level of regulatory oversight, by the GTR.

Impact of option 1:

The Government would not incur any increased costs. Also, business and researchers would not be likely to incur a significant impact as a result of this option. This is because this option maintains the status quo and ensures that organisms that have not previously been considered by GMAC to be GMOs are not treated as GMOs under the new system of regulation. Consumers are not likely to be impacted by this option. In respect of the community, this option was discussed at length during public consultations on the Regulations. Most stakeholders recognised that there would be no, or minimal, negative impact on the health and safety of people or the environment.

Impact of option 2:

The government would be expected to incur significantly increased costs. This is because all of the organisms that have previously been outside the control of the GMAC system would require regulatory oversight. It Would also impact on Australia's trade with other countries because organisms (such as plants formed by in vitro fertilisation) which are currently traded freely between countries, would not be able to be imported into Australia without prior approval from the GTR. Furthermore, it would be impossible for government to effectively regulate some of the organisms, as these changes to their genetic make-up can occur in nature (ie. without human intervention).

Similarly, business and researchers would incur significantly increased costs. This option would adversely effect a number of businesses that are not otherwise caught under the regulatory scheme. Because these organisms have not been regulated by GMAC (or other regulators) in the past, it is not possible to provide an accurate estimate of the number of activities or organisations that would be effected. However, it is expected that it would be in excess of 3000 projects in various fields, including plant breeding, university laboratory research and medical research.

This option could effect consumers as the need to meet new regulatory requirements may cause some key researchers undertaking fundamental or proof of concept research (particularly medical researchers) to withdraw from gene technology work. Furthermore, higher costs of regulation could affect product prices.

Also, this option poses a cost to the community by suggesting that such organisms (including those that exchange genetic material in nature) are inherently unsafe and require regulatory oversight. This could prove damaging to the community's confidence in the new regulatory system, which follows good regulatory practice by focusing on GMOs and dealings that may pose a risk to the health and safety of people and the environment.

Conclusion and recommended option:

The Regulations incorporate Option 1. This Option is the only tenable option and ensures that activities that are not strictly gene technology are not subject to unnecessary and costly regulation that cannot be justified on the basis of risks to public health and safety and the environment.

(b) Exempt dealings with GMOs

Section 32(3) of the Act provides that certain dealings with a GMO may be prescribed as exempt dealings. There are two options for dealing with exempt dealings with GMOs in the Regulations.

Option 1: Retain the current GMAC exemptions in the Regulations with certain modifications.

The GMAC Guidelines for Small Scale Genetic Manipulation Work set out the work that is exempt under the voluntary GMAC system. The GMAC exemptions have been developed over the past 25 years, based on the experience of the Committee (including predecessors) in assessing GMO dealing applications.

The exemptions apply to a limited number of dealings with GMOs undertaken within contained facilities that:

- have been assessed over time as presenting no significant biosafety risks to public health and safety (including occupational health and safety) or the environment; and

- do not involve intentional release of a GMO into the environment.

This Option would involve reflecting the tenor of the current exemptions in the Regulations, but amending the wording of the exemptions to ensure that:

- they are consistent with the legislation;

- they are sufficiently certain to enable organisations to rely on them and to enable them to be enforced by the GTR; and

- the wording of the GMAC exemptions is narrowed in some instances to ensure that the exemptions do not unintentionally exempt a broader range of activities than is intended (and only cover those dealings that can be shown to present negligible risk).

Option 2: No exempt dealings or notifiable low risk dealings prescribed in the Regulations (ie. all GMO dealings to be licensed).

During consultation on the Regulations, a number of community stakeholders suggested that there should be no exempt dealings with GMOs set out in the Regulations and that all dealings with GMOs should be licensed by the GTR following a detailed case by case risk assessment.

Impact of option 1:

The impact of option 1 on the Government would be minimal. This is because this option implements the risk management approach which is at the heart of the new system, whereby government resources expended in regulating known low risk activities are minimised.

Furthermore, the majority of businesses and researchers would not experience increased costs. However, as a result of redrafting and clarifying the scope of the exemptions, in some cases the exemptions have been narrowed slightly and, as such, costs may be increased for some organisations whose work will now be treated as a Notifiable Low Risk Dealing (NLRD). It is estimated that a small, indeterminate number of projects (of 5000) (ie. nominally estimated at less than 50 projects) would be affected by the changes. For example, the exemption would not apply to those dealings with gene-knockout mice (that is, mice whose genetic modification involves deletion or inactivation of a specific gene) where an advantage is conferred on the adult animal (this would be a rare occurrence). In these cases, the administrative burden would be small because the organisation concerned would have the necessary information readily available. In addition, the OGTR would make available resources to minimise the additional burden on those organisations.

Consumers would not experience any significant impacts.

The Community would not experience any significant impacts under this option.

Overall, this option aligns with the status quo as developed by GMAC, based on many years of experience.

Impact of option 2:

The impact of this option on the Government would be significant. This is because approximately 5000 projects that are currently exempt or notifiable (category B under the voluntary GMAC system) would require licensing by the Regulator. This would consume significant resources, and

would undoubtedly detract from the important work of the Regulator in respect of higher risk dealings with GMOs which are to be licensed. It is estimated that the increased cost to government would be in the order. of tens of millions of dollars.

Business and researchers would experience a significant impact under this option. This is because organisations currently conducting dealings that are exempt or notifiable under the GMAC system would need to submit comprehensive applications to the Regulator seeking a licence, as distinct from an exemption or NLRD. The details required to obtain a licence are of a higher order than the details associated with obtaining an exemption or approval as a NLRD. In particular, a licence provides for the intentional release into the environment of the GMO (eg: conducting of field trials), or for the undertaking of high risk contained research, whereas an exemption or NLRD approval does not authorise an intentional release of a GMO into the environment. As such, the evaluation and consultation requirements prescribed in the *Gene Technology Act 2000* are more significant in relation to these dealings, including potentially longer time delays and greater information-gathering requirements.

Work on many of those projects would need to be suspended while the GTR examined this information and conducted assessments. This would be likely to effect the approximately 5000 projects and would be likely to impose significant additional costs on business and researchers to compile the proposals. It is not feasible to determine the approximate cost of preparing proposals across such a wide range of projects. However, it is foreshadowed that it would be a very considerable cost to business and researchers and not financially feasible in respect of contained fundamental and proof of concept research.,

Consumers would not experience any adverse impact as exempt dealings and NLRDs, undertaken in contained facilities, have been assessed over time as posing negligible risks to the health and safety of people or the environment. There would, however, be the factor of increased cost to consumers as a result of the licensing cost being applied to marketed GMO products.

The Community could perceive that action under this option would indicate that the government now considered all GMOs to require some level of regulation at a licensing standard. This would fuel existing fears amongst some sections of the community that GMOs are inherently or intrinsically unsafe. In particular, the potential risks derived from exempt dealings or NLRDs are low because neither involve release of a GMO into the environment or commercialisation of the GMO for human or animal use. Thus, the potential impact of this option would be a negative one if the cost implications of requiring licensing for exempt dealings and NLRDs meant any inhibition on work in the areas, for example, of fundamental and proof of concept medical research.

Conclusion and recommended option:

The Regulations incorporate Option 1.

[Note: It is proposed that the Gene Technology Regulations require that exempt dealings under the *Gene Technology Act 2000* can only be undertaken in contained facilities that comply with the Australian *Standard* AS/NZS *2243.3:1995 (Safety in laboratories:. microbiology). A* lesser containment standard would not secure the minimal level of biosafety risk required for these dealings. This should not have a significant impact on businesses and researchers, as the majority of laboratories dealing with GMOs, including teaching and University research laboratories, are already certified to a higher containment level (PC2) than that specified by AS/NZS 2243.3:1995, as they are often dealing with higher risk category dealings at the same time, and also as an added safety precaution for staff. Indeed, the CSIRO stated in its submission that it is more convenient to have their laboratories certified to a higher standard.

Those organisations operating facilities that are not of a higher containment level would, in the main, be schools that are teaching gene technology. However, most of these organisations still ensure compliance with AS/NZS 2243.3:1995 for legal reasons, as the Standard has legitimacy

being of the AS/NZS series. The Standard is specifically designed so that school laboratories can comply with its requirements.]

(c) Notifiable Low Risk Dealings with GMOs

Under the current administrative arrangements overseen by GMAC, GMAC has issued guidelines setting out "Category B" activities that require Institutional Biosafety Committee (IBC) assessment, and notification to GMAC, before the work commences.

It is intended that the category of notifiable low risk dealings (NLRD) prescribed under the legislation allows for "Category B" dealings. In particular, NLRDs are dealings that the Regulator considers to be of particularly low risk, but which do not warrant exemption from the provisions of the Act. The low risk will usually be because the GMO is biologically contained (ie. it has a reduced ability to survive or reproduce in the open environment), is not pathogenic and does not produce new proteins that are of high risk because they are toxic. The limited differences are that under the statutory scheme, the organisation must be accredited, and if working with human pathogens, the work must be undertaken in accordance with the relevant Australian standard.

The Act allows regulations to be made setting out categories of work with GMOs that are NLRDs and conditions that must be complied with in relation to NLRDs.

Option 1: Existing GMAC Category B activities prescribed in the regulations as NLRDs.

This option would involve basing the list of NLRDs on the GMAC Category B dealings. Such dealings with GMOs:

- have been assessed over time as presenting minimal biosafety risks where such risks can be properly managed through containment of the GMO in a laboratory certified to Physical Containment Level 2. For example, some of the factors considered in assessing a GMO to be of low risk (with the low risk able to be managed through containment measures) include the extent to which the GMO is 'biologically contained' (because it has a reduced ability to survive or reproduce without human intervention) and the properties of the GMO including the inability of the GMO to be a pathogen or pest or produce toxic proteins; and

- do not involve the intentional release of a GMO into the environment.

Furthermore, the regulations would require that dealings with such GMOs must:

- be assessed by the applicant's W;

- be notified to the GTR;

- be conducted within conditions of physical containment (PC2);

- if transported, be transported only in accordance with strict Guidelines for transportation issued by the GTR; and.

- not involve release of the GMO into the environment.

In essence, the status quo of GMAC Category B activities, including notification and, for example, transportation requirements, would be retained in these proposed NLRDs requirements. However, the wording of the GMAC Category B activities would be narrowed in some instances so as to ensure that the NLRDs do not unintentionally catch a broader range of activities than is intended.

Option 2: No notifiable low risk dealings prescribed in the Regulations.

During consultation on the draft Regulations, some community stakeholders suggested that there should be no NLRDs with GMOs set out in the Regulations, and that all dealings with GMOs should be licensed by the GTR following a detailed case by case risk assessment.

Impact of option 1:

The impact of option 1 on the Government would be minimal. The option ensures that such activities attract an appropriate level of regulatory oversight, which based on GMAC experience, accurately reflects the level of risk posed by such dealings.

In respect of business and researchers this option would not have a significant impact, as the key aspects of the current administrative system are maintained. In essence, the status quo is maintained for business and researchers

Consumers would experience no, or minimal, impact under this option.

The Community would experience no, or minimal, impact under this option.

Impact of option 2:

The impact of this option on the Government would be significant. The effect would be that approximately 1700 projects that are currently Category B work (under the voluntary GMAC system) and approximately 300 new projects per annum would require licensing by the Regulator. This would consume significant resources and detract from the important work of the Regulator in respect of higher risk dealings with GMOs. It is estimated that the increased cost to government would in the first year range from $15 to 20 million, and in each subsequent year approximately $2.5 to 3 million.

The impact on business and researchers of this option would be significant. Not only would industry bear the significant costs of the Regulator (if cost recovery is introduced) but industry would also bear significant internal costs associated with preparing applications seeking a licence for the work. The application requirements for licences are significantly more detailed than those for NLRDs.

Consumers would be impacted upon by this option where a decision was made to fully or partially cost recover the operations of the regulatory system, and thus business would need to recoup those costs from consumers.

In respect of the Community, this option would not be likely to have a significant impact, other than that taxpayers would bear the cost in the absence of a cost recovery regime.

Conclusion and recommended option:

The Regulations incorporate option 1 for the following reasons:

- existing GMAC IBC arrangements for handling small scale genetic manipulation work in a physical containment facility (ie. NLRDs) have operated efficiently and effectively for some time. It is a procedure with which gene technology research organisations are familiar and as such costs of compliance are unlike to increase significantly;

- the costs of requiring all NLRDs to be licensed would be in the range of $15 to 20 million with no expected benefits to the community (in terms of protecting the health and safety of people and the environment).

[Note: The referencing of *Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology).* under either option 1 or 2, as a condition relating to NLRDs will not have a significant ,impact on businesses and researchers. This is because only a small section of the Standard, relating to vaccination, is actually called up in the Gene Technology Regulations, and

these vaccination requirements are already recommended by GMAC. These particular requirements are unlikely to vary significantly in the future, as they already require vaccination when dealing with human pathogens, and organisations have systems in place to ensure that such vaccination is undertaken. There are no known instances of non-compliance with the vaccination requirements.]

(d) Licensed dealings with GMOs - Information requirements for applications

Section 40 of the Act provides that an application submitted by a person for a licence authorising dealings with GMOs must contain such information as is prescribed in the Regulations (if any) and such information as is specified in writing by the Regulator.

Option 1 - Prescribe detailed information in the Regulations.

This option would involve prescribing in Schedules to the Regulations very detailed information that the Regulator requires from the applicant in order to make an assessment of an application to deal with GMOs.

This approach is based on:

- the existing GMAC Guidelines;

- submissions made on the *Gene Technology Act* 2000 and on the August 2000 and January 2001 draft of the Gene Technology Regulations; and

- international precedent, including the European Council Directive 90/220/EEC.

This option would also be supplemented by a requirement that the applicant must take account of the risks the proposed GMO dealing may incur in relation to the health and safety of people and the environment. If the applicant is not able to provide all relevant data and references, the Regulations require that the applicant must state what information is incomplete or unavailable, indicate the significance of the information, and in the absence of comprehensive scientific data provide a theoretical analysis of any risks posed.

Option 2 - Prescribe in the Regulations very general classes of information required by the Regulator.

This option would mean that instead of prescribing very detailed information requirements in the Regulations, the Regulations would be a lot simpler and would simply state that the Regulator required information against 6 key headings (eg. the genetics of the GMO, risk assessment information, risk management information etc.) This is a less prescriptive approach than option 1, and leaves responsibility with the organisation for identifying the types of information required to establish the safety of the proposed dealings with the GMO.

Impact of Option 1:

This option provides advantages for government in that the GTR will be provided with certain baseline information by. all applicants. This arrangement may make it easier to assess applications, meaning that assessment processes can commence shortly after the receipt of the relevant application without the need for the Regulator to pursue further information from the applicant. This will help to make the process more transparent, as all proponents, irrespective of levels of sophistication, will be required to submit certain information.

Business and researchers would be expected to experience essentially existing costs. This is notwithstanding that the new arrangements are a composite of the existing GMAC Guidelines, ideas presented in submissions on the draft regulations, and international precedent. However, the major influence on the development of option 1 would be the GMAC Guidelines. The advantage for businesses and researchers under this option is that it provides applicants with a

substantial amount of guidance about the information required by the Regulator. During consultations on the Regulations this type of guidance information was identified as a high priority by many businesses and researchers. However, the disadvantage is that by being prescriptive, it may be necessary to change the requirements over time to reflect the Regulator's evolving requirements and industry practice.

Consumers would not experience any, or only minimal, impact as a result of this option.

The Community would not experience any, or only minimal, impact as a result of this option. An exception would be that this option provides a benefit through stressing the 'arms length' nature of the relationship between the GTR and industry and researchers.

Impact of Option 2:

The impact of this option on the Government is that the GTR would be required to undertake a far more strenuous examination of exactly what information has been provided before the risk assessment process could commence.

In respect of businesses and researchers, it is anticipated that there could be some advantages for larger business, on the proviso that they have a clear idea of exactly what information is relevant to assessing and managing any risks. Conversely, smaller organisations, particularly research organisations, may be significantly disadvantaged and this option may affect their competitiveness within a global science system. This, ultimately, would affect the small to medium-sized Australian enterprises that stand to benefit from Australian science.

The experience of other regulatory bodies, for example, the National Registration Authority for Agricultural and Veterinary Chemicals, is that industry wants to know what information is required for evaluation so as to provide a full data package for evaluation. In the case of an application submitted to the Regulator for licensing a GMO dealing, the information requirements will need to meet the statutory requirements for a licence to be granted. The information could be provided under either option 1 or 2. However, it is be foreshadowed that under option 2 there would be more 'clock-stop' situations and disputes over what information is required. This is because the Regulator has certain statutory duties which must be fulfilled. Thus it appears on balance to be appropriate to set out for industry and researchers the information required to readily facilitate determination of an application for licensing a GMO dealing.

Consumers are not likely to experience any significant impact beyond a potential impact on the pricing structure of GMO products arising from changes in the uptake of research outcomes between small Australian and large multinational organisations.

Also, this option would be expected to have a negative effect on building community confidence in the regulatory system. Furthermore, the mixed format of the information provided by applicants could make it more difficult for community members to build some expertise in this area so as to allow them to comment on proposals.

Conclusion and recommended options:

The Regulations incorporate option 1.

(e) Evaluation of applications for licence, accreditation of organisations and certification of facilities - Time limits

Option 1: No time limits prescribed in the legislation

The effect of this would be that the Regulator would not be limited as to the time period during which he/she must decide an application for a licence, accreditation or certification.

Options 2: Time limits prescribed in the legislation. Time limits being: 90 days for applications for accreditation and certification, 90 days for applications not involving intentional release of a GMO into the environment, and 170 days for applications involving intentional release of a GMO into the environment.

The timeframes proposed (as detailed above) have been:

- based predominantly on the experiences of GMAC in evaluating applications over a considerable number of years. For intentional releases the proposed timeframes are slightly longer than the former GMAC timeframes (single round of public consultation) because of the new requirements in the legislation for two rounds of public consultation on applications. The timeframes are, however, equivalent to the GMAC timetable implemented during late 2000 where two rounds of public consultation are undertaken;

- developed using comparisons to existing regulators. For example, the NRA takes 6 months for evaluation of applications for the registration of agricultural and veterinary chemicals. In addition, there are other allied evaluations, which provide an evaluation period of 8 months, eg. application to vary a condition of approval of a label to permit a change of a technical nature.

Option 3: Time limits prescribed in the legislation with capacity for "clock-stops"

This Option would mirror option 2 (in terms of days set for evaluations) but would also include "clock stops". The clock would stop for periods when the Regulator is awaiting information requested from the applicant, during public hearings (which have the capacity to introduce a number of unknown variables), during consideration of an application to declare certain information confidential commercial information, and while the GTR is awaiting advice from the Gene Technology Ethics Committee (time frame for reply to be stipulated by the Regulator).

Option 4: Requirement that applications be submitted by one of 6 dates (for intentional release of a GMO into the environment).

In the first consultation draft of the Regulations (August 2000). it was proposed that applications for intentional release be deemed to have been submitted on the first of six dates after the application is submitted. This was consistent with the approach currently adopted by GMAC.

Impact of option 1:

For government, this option would have some advantages, since it would allow unlimited time for consideration of applications. This would be consistent with current GMAC arrangements whereby there are no written administrative guidelines for timing. There are, however, informal evaluation times, refer option 2.

For business and researchers, this option would have enormous costs implications. This is because there would be no certainty about when the GTR would make a decision, for example on a proposed licensed dealing, thus it would make business planning extremely difficult. This would be likely to provide a disincentive to research and commercialisation activities in Australia, and make it more likely that larger corporations would conduct their activities overseas.

For consumers, this option would be likely to create additional costs to consumers, where the GTR took a long time to consider applications. As larger organisations would be likely to undertake substantial research and commercialisation activities overseas if option 1 was adopted, this could also reduce consumer choice because fewer GM products may be marketed in Australia.

During consultations, certain sections of the community stated a preference for option 1.

Impact of option 2:

This option would have potential cost implications for Government, as a decision would always be required within the statutory timeframe, even where the GTR required additional information to make that decision. As such, option 2 could compromise the integrity of the regulatory system. For example, where an applicant took 30 days to provide additional information on a proposed licensed dealing, the GTR would still be forced to make a decision within 170 days.

For business and researchers, this option would offer a very high level of certainty.

Consumers, under this option, might have some concerns about the GTR's need to rely on industry-provided information.

Community groups did not support this option as it would appear likely to create a perception that the GTR was unduly reliant on the quality of applications submitted by proponents.

Impact of option 3:

Government would experience advantages under this option, since it allows adequate time for a full consideration of an application, but also makes provision for additional time under limited circumstances. This would ensure that the GTR is accountable for efficiently managing its own processes, but the integrity of those processes will not be unduly affected by outside factors beyond the GTR's control, such as the need for an applicant to provide further information.

Business and researchers under this option would be encouraged to carefully manage their responsibilities in respect of application processes, since time will be lost where further information is required. Thus, applications should be as comprehensive as possible.

Consumers, as a result of this option, would be likely to increase their confidence over time, and should not have major costs to consumers.

The transparency of this option would build community confidence in the national regulatory system over time.

Impact of option 4:

Government would experience some advantages under the 'batched' approach of this option as it would facilitate the bulk processing of each common stage of the applications, eg. mailing applications to evaluators for consideration. However, it could also lead to high peak workloads for the Regulator.

For business and researchers, this option could potentially present disadvantages by adding artificial deadlines for applications and introducing a lack of flexibility for applicants.

This option would have no, or only minimal, impact for consumers.

This option would be expected to stretch community resources because there would be 'peak' workload times when community members would be expected to provide input on a large number of applications over a short period of time. For example, each application is likely to require a different response, and if there are several to be responded to in the same 30 day period, responses received during public consultations suggested that this would be more likely to disadvantage the public than to advantage it. In turn, this would be likely to damage community confidence in the national regulatory scheme as the peak workload would, in effect, undermine the community's scope for involvement because of pressure of time to provide comments.

Conclusion and recommended option:

The Regulations incorporate option 3. Option 3 strikes an appropriate balance between the need for the GTR to provide a comprehensive regulatory assessment process and the interests of

business and researchers, the community and consumers in regulatory certainty. There would be a nett benefit to the community as a whole.

(f) Certification of facilities and accreditation of organisations - Transitional arrangements

The *Gene Technology Act 2000* (Division 5 of Part 12) describes transitional provisions to assist in the transition of the current voluntary arrangements overseen by GMAC to the new regulatory system proposed in the Act.

In particular, section 190 provides that if the GMAC has issued an advice to proceed immediately before the commencement of the Act, the advice is deemed to be a licence under the Act for a period of two years, or when the advice to proceed expires, whichever is the sooner.

One of the issues that was not addressed in the Act was transitional arrangements for accreditation of organisations and certification of facilities.

Option 1: Prescribe transitional arrangements in the Regulations for accreditation of organisations and certification of facilities.

Under this option, Regulations would provide that:

- all existing PC2 facilities (excluding PC 2 Large Scale facilities) notified in writing by GMAC before the commencement of the Act (that is, all existing ones) will be deemed to be certified under the *Gene Technology Act 2000* for a period of two years after the commencement of the legislation. This "deemed certification" would be conditional upon the facility being maintained in accordance with the GTR's guidelines for certification that would mirror the existing GMAC guidelines for containment facilities. These arrangements would apply to approximately 1300 existing PC2 facilities.

- all existing PC3, PC4 and PC 2 Large Scale facilities and other facilities notified in writing by GMAC before the commencement of the Act will be deemed to be certified under the *Gene Technology Act 2000* for a period of one year after the commencement of the legislation. As for PC2 facilities, this "deemed certification" would be conditional upon the facility being maintained in accordance with the GTR's guidelines for certification that would mirror the existing GMAC guidelines for containment facilities.

- all organisations that receive a notice from the GMAC before the commencement of the legislation, are taken to be accredited organisations for two years. To maintain their "deemed accreditation", organisations would need to comply with guidelines issued by the GTR.

Before the end of the transitional period, organisations and managers of facilities would need to apply to the GTR for recertification of the facilities and reaccreditation of the organisation against criteria set by the Regulator. It is also proposed that the Regulator will implement a rolling schedule of re-approvals to minimise peak work periods.

Option 2: No transitional arrangements for organisations that currently have an [BC or facilities that have been certified by GMAC/IBCs.

Under this option, organisations dealing with GMOs and all facilities in which work with GMOs is conducted would be required to be accredited/certified by the Regulator from the first day of operation of the new legislation. The effect of this would be, that from 21 June 2001 organisations would not be able to undertake dealings with GMOs until they had been accredited by the GTR and their facilities certified by the GTR. This would affect approximately 120 organisations (undertaking in excess of 2000 distinct projects), 1300 PC2 facilities, 22 PC3 facilities and one PC4 facility.

Impact of option 1:

Government. The cost impact under this option would be minimised because it provides for a staged implementation of the new arrangements.

The cost imposed on businesses and researchers under this option is not likely to be significant. However, during the transitional period industry and researchers will have to comply with guidelines for accreditation and certification issued by the Regulator. As these will be based on the current GMAC Guidelines, they are unlikely to impose any significant costs of compliance on industry.

The direct impact of this option on consumers and the community would be minimal.

Impact of option 2:

From the Government's perspective, this-option is not administratively acceptable. The effect of this option is that the Regulator would receive approximately 1300 applications in respect of PC 2 facilities and also be required to determine applications for certification of PC 3 and PC 4 facilities. The applications would need to be processed within the 90 day statutory timeframe. Similarly, over 120 organisations would apply for accreditation and these would also need to be processed within 90 days. This would impose an unmanageable burden on the Regulator.

In respect of businesses and researchers, this option would have a significant effect. This is because it would effectively mean that all work with GMOs would halt until the organisation was accredited by the GTR and the facilities certified under the Act. Under this scenario work with GMOs could cease for in excess of 5 months. It has not been possible to determine the cost to businesses and researchers.

Concerning consumers and the community, the direct impact of this option would be minimal. However, it could have flow-on effects to consumers if it resulted in GMO work being suspended for a prolonged period. During consultations, the community recognised the benefits of grandfathering existing certifications and accreditations, but supported an approach whereby after a certain defined period of time, facilities and organisations would be reassessed by the Regulator as proposed in option 1.

Conclusion and recommended option:

The Regulations incorporate option 1.

(g) Committees

The *Gene Technology Act* 2000 establishes three statutory Committee - the Gene Technology Technical Advisory Committee (GTTAC) the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC).

The Act provides that the Regulations may prescribe matters relating to.

- the members of the Committees (including terms of appointment, disclosure of interest etc); and

- the operation of the Committees (including procedures for convening meetings, the way matters are dealt with, reporting requirements etc).

An issue is the need for some limits to be placed on Committees to ensure that the costs of running the Committees are not excessive.

It is therefore proposed that certain disciplines be imposed through the Regulations to ensure that the Committees are able to operate effectively and fulfil their functions in the most costeffective manner.

Related options and impacts are as follows:

- rather than all meetings being held face-to-face, there is capacity for Committees to meet by videoconference or teleconference. The Regulator, through the Department of Health and Aged Care, would have available such facilities for committee work. In respect of GTTAC, videoconferencing of a 2 day meeting would attract a saving of approximately $10,000 to 15,000, similarly GTCCC and GTEC would attract a saving of $4,000 to 5,000. Teleconferencing would attract a higher saving because the major infrastructure cost would be the cost of the SDT call to each Committee member.

- rather than the calling of face-to-face meetings being at the discretion of the Committees, such face-to-face meetings of the Committees being determined in consultation with the Regulator at the beginning of each year, and no additional face-to-face meetings held without the agreement of the Regulator. This ensures that the Committees have adequate face-to-face meeting time (to enable them to fulfil their functions), without the potential costs being open-ended; and

- requirement that the Committees act with as little formality and as quickly as the requirements of the legislation and a proper consideration of the issues allow.

These measures are intended to keep costs to a minimum level necessary for the functioning of the Committees, with a positive impact on government or, under cost recovery, on business and researchers. As such, these measures address the issue raised during the consultation process of the need to constrain the cost of operating the Committees.

Consultation

a) The consultation process

In August 2000, an early draft of the Regulations was released for public consultation. The IOGTR received over 60 submissions suggesting changes to the regulations and each of these submissions was responded to individually. The draft regulations were also made available to the Senate Community Affairs References Committee and other Parliamentarians. A number of recommendations to improve the regulations were made by the Committee and by Senators during debate of the Gene Technology Bill 2000.

Suggestions made by stakeholders were referred to both the Commonwealth State Consultative Group on Gene Technology (a body of senior government officials overseeing the development of the legislation) and the Genetic Manipulation Advisory Committee (GMAC), for consideration and advice.

After detailed consideration of the issues, a revised draft of the regulations was prepared and circulated for comment in January 2001. The draft Regulations were accompanied by an Explanatory Guide explaining the rationale for the changes made to the first draft of the Regulations and seeking further comments. The Regulations and the Explanatory Guide were placed on the IOGTR website, direct mailed to approximately 4000 individuals and organisations who had registered (with GMAC or the IOGTR) an interest in receiving information on the regulation of GMOs and advertised in newspapers throughout Australia.

Written submissions were invited from interested organisations and individuals. In addition, consultation on the revised Regulations were conducted in each capital city in Australia throughout February and March 2001. Invitations to the consultations were sent to approximately 3500 organisations and individuals. Over 340 people attended the face-to-face consultations and some 84 written submissions were received on the Regulations.

b) Results of the consultation on the Regulations in relation to each of the key components of the Regulations

Organisms that are not GMOs and Exempt Dealings with GMOs

A broad range of comments were received in relation to this component of the Regulations. Some submissions called for there to be no exemptions under the new regulatory scheme, while others were very specific in their desire to have certain dealings made exempt or included as a NLRD. These were not segregated into particular stakeholder groups, with, for example, some consumer groups accepting that certain organisms should be exempt from the definition of GMO, and some researchers offering suggestions for limiting the exempt classifications in relation to particular dealings (eg: with knockout mice).' Others called for exempt dealings to be undertaken in high containment facilities, and for Institutional Biosafety Committees to make decisions as to whether a dealing is exempt, rather than leaving these decisions up to the researchers.

Notifiable Low Risk Dealings with GMOs

Again, a broad range of comments were received in relation to this component of the Regulations. Some submissions called for NLRDs to be carried out only in high containment level facilities, while others called for all dealings with GMOs to be licensed by the GTR. A number, as in the case of exempt dealings, were very specific in their desire to reclassify certain NLRDs as either exempt or requiring a licence. The Regulations reflect an approach that attempts to maintain the status quo in relation to current GMAC Category B activities, with some minor amendments made as a result of consultations, so as to ensure protection of the environment and of public health and safety. There was less concern and comment expressed over this category of dealings than in relation to exempt dealings, as NLRDs are subject to greater legislative scrutiny and will be notified both to the Regulator and to the public.

Licensed dealings with GMOs - Information requirements for applications

The vast majority of submissions were supportive of the information requirements placed on applicants under the Regulations, including those received from researchers and businesses. This latter group could see that these requirements mirrored to a significant extent those already required by GMAC, and accepted, by and large, that the legal controls over dealings with GMOs had to be rigorous and accountable. In fact, some researchers and businesses, along with many other submissions, offered suggestions for further information requirements which should be prescribed in the Regulations. Many of these suggestions were included in the final version of the Regulations. Others believed that the list of prescribed information requirements seemed to be thorough, as well as providing a successful hybrid of detailed lists with flexible application. There was also a call to attempt to ensure that these requirements are harmonised with those required by other regulatory agencies.

Evaluation of applications for licence, accreditation of organisations and certification of facilities - Time limits

A full range of comments was received in relation to this component of the Regulations. Some organisations believed that the time limits prescribed were too long, especially in such a competitive area. It was claimed that these time periods would allow overseas colleagues to respond to new experimental approaches and the like more rapidly, thereby hindering the development of a "Smart Australia". Others believed that the time limits, as prescribed, would make it difficult for some organisations to obtain adequate input from their members, and do not provide the Regulator with enough flexibility to, for example, commission research. The stopclock mechanisms were seen by some as a positive step for the protection of the public and of the environment. Still others felt that the time limits were reasonable, but requested that some disciplines be placed on the stop-clock mechanisms so as to ensure certainty in the application process. The 'batching' calender approach to applications was also raised as lacking flexibility and would result in a 'lumpiness' to the seeking of public comment on the applications.

On balance, the majority of stakeholders supported the time limits prescribed in the Regulations, including the associated clock stop arrangements.

Certification of facilities and accreditation of organisations - Transitional arrangements

There was wide support for the implementation of transitional arrangements for accreditation and certification. Some submissions did not support the accreditation of organisations. However, these comments related to the concept of accreditation as a whole, as prescribed in the *Gene Technology Act 2000,* and not to the implementation of transitional arrangements to cover those organisations currently undertaking dealings with GMOs.

Committees

A number of submissions and other comments received in relation to the proposed committees related to the quorum required in order to make decisions. Also mentioned were the terms of appointment of the Chairs of the committees, the perceived effectiveness of the disclosure of interest provisions, and the processes by which the committees should be able to obtain information. In particular, some submissions expressed the view that there should be defined operational guidelines for the committees, while others wanted the committees to be free to operate as they choose. A number of commentators felt that the disclosure of interest provisions should be extremely broad, with some commentators going so far as to state that persons with such interests should not be members of the committees at all.

On balance, the majority of stakeholders supported changes made to disclosure of interest provisions from the first draft to the second draft of the Regulations.

6. Implementation and Review

Implementation

The new national system for the regulation of gene technology and GMOs will commence on 21 June 2001. The proposed Gene Technology Regulations will also come into effect at this time.

Review

Section *194* of the *Gene Technology Act* 2000 provides that the Ministerial Council on Gene Technology (established under the Inter-Governmental Agreement on Gene Technology) must cause an independent review of the operation of the Act, including the structure of the Office of the Gene Technology Regulator, after *4* years operation of the Act. This review will include a consideration of any delegated legislation that is part of this legislative scheme. The Report of the review is to be tabled in Parliament.

In addition, a person can, at any time, request the Regulator to review the exempt and notifiable low risk dealings prescribed in the Regulations, with a view to either adding or removing certain dealings with GMOs from those categories on the basis of risk to health and safety of people or to the environment.

7. Competition Principles Agreement Statement

In respect of conducting a 'Legislation Review' as set out under the Competition Principles Agreement (11 April 1995), the guiding principle is that legislation (including Acts, enactments, Ordinances or Regulations) should not restrict competition unless it can be demonstrated that:

- the benefits of the restriction to the community as a whole outweigh the costs; and
- the objectives of the legislation can only be achieved by restricting competition.

However, it is notable that the provisions of 'Interpretation' relevant to that Agreement provide at clause 1(3) that:

Without limiting the matters that may be taken into account, where this Agreement calls:

(a) for the benefits of a particular policy or course of action to be balanced against the costs of the policy or course of action; or

(b) for the merits or appropriateness of a particular policy or course of action to be determined; or

(c) for an assessment of the most effective means of achieving a policy objective;

the following matters shall, where relevant, be taken into account:

(d) government legislation and policies relating to ecologically sustainable development;

(e) .....

(f) government legislation and policies relating to matters such as occupational health and safety, ...

(g) .....

(h) the interests of consumers generally or of a class of consumers;

(i) .....

The Regulation Impact Statement for the Gene Technology Bill 2000 explained the extent to which the new regulatory system for genetically modified organisms restricts competition. The new regulations do not add to this.

Do the benefits to the community outweigh the costs?

The benefits of introducing this new regulatory system, both for the community at large, and for industry, are set out in the Regulation Impact Statement for the Gene Technology Bill 2000. The costs to the community were also explored in that document. It was concluded that, given the substantial benefits of the new regulation both to the community, in terms of the protection of health and safety and the environment, and to industry, in terms of providing a pathway to market for GMOs judged to be safe, the benefits of the system will outweigh the costs of regulation.

The proposed regulations to be made under the new *Gene Technology Act 2000* do not add substantially to these considerations, as they are not affecting the fact that there will be assessment of GMOs by an independent Regulator, and they ensure a level of regulation that is commensurate with the risks involved. The information requirements prescribed in the Regulations are on a par with those required in other regulatory systems, for example in the European Union and New Zealand, and the timeframes equivalent with those of similar domestic regulators,

The notion of varying the level of regulations in accordance with the risks involved is already prescribed in the Gene Technology Act, and has been mirrored in recent international legislation, such as the new European Directive on GMOs. The prescription in the regulations should therefore not serve to lower the community's confidence in the regulatory scheme.

Can the Governments objective only be achieved through restricting competition?

As detailed in **Part 1 - Background** to this RIS, an administrative scheme (based around the Genetic Manipulation Advisory Committee) has been operating for a number of years providing oversight in relation to research with GMOs, field trials involving GMOs and the commercial release of GMOs not regulated under existing regulatory schemes. This administrative scheme was based on voluntary compliance by industry and as such did not restrict competition.

However, as also outlined in this Regulation Impact Statement, there are a number of problems associated with continuing a voluntary administrative scheme of this nature (including regulatory uncertainty, an inability to enforce conditions and compliance with GMAC requirements etc).

The Regulation Impact Statement for the Gene Technology Bill 2000 discusses Governments' examination of a range of options for addressing these problems, and explains that the approach finally adopted, whereby high risk dealings must be licensed by the Regulator and undertaken within accredited organisations (who have an IBC) was the only option that ensured that a number of important criteria were met. These criteria included a comprehensive assessment of the risks posed to public health and safety and the environment in relation to dealings with GMOs; a high level of transparency and stakeholder involvement in decision making; and regulatory certainty for industry in terms of timeframes and assessment processes.

The regulations to be made under the *Gene Technology Act 2000* do not detract from this reasoning and, if anything, ensure that the new regulatory system can adequately meet these criteria by, for example:

- prescribing information requirements for the undertaking of risk assessments;

- prescribing timeframes for the undertaking of risk assessments;

- ensuring advisory committee procedures-are transparent; and

- prescribing those dealings which must be licensed, and the conditions (including containment) under which lower risk dealings can be undertaken.